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PART I

FEDERAL REGISTER

THE NATIONAL ARCHIVES OF THE UNITED STATES
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Washington, Tuesday, December 20, 1955

TITLE 5—ADMINISTRATIVE PERSONNEL

Chapter I—Civil Service Commission

PART 6—EXCEPTIONS FROM THE COMPETITIVE SERVICE

DEPARTMENTS OF DEFENSE AND NAVY

Effective April 1, 1956, paragraph (k) (1), (2), (3) is added to § 6.104 and paragraph (a) (4) is added to § 6.106 as set out below.

§ 6.104 *Department of Defense.* * * *

(k) *Entire Department (including the Office of the Secretary of Defense and the Departments of the Army, Navy, and Air Force).* (1) Until December 31, 1960, professional positions in Military Dependent School Systems overseas.

(2) Until December 31, 1960, positions in Attaché Systems overseas.

(3) Until December 31, 1960, positions of clerk-translator, translator, and interpreter overseas.

§ 6.106 *Department of the Navy*—(a) *General.* * * *

(4) Until December 31, 1960, positions in the Saipan District.

(R. S. 1753, sec. 2, 22 Stat. 403; 5 U. S. C. 631, 633; E. O. 10440, 18 F. R. 1823, 3 CFR 1953 Supp.)

UNITED STATES CIVIL SERVICE COMMISSION,
[SEAL] WM. C. HULL,
Executive Assistant.

[F. R. Doc. 55-10151; Filed, Dec. 19, 1955; 8:46 a. m.]

PART 6—EXCEPTIONS FROM THE COMPETITIVE SERVICE

FEDERAL HOME LOAN BANK BOARD

Effective upon publication in the FEDERAL REGISTER, paragraph (b) of § 6.142 and paragraph (d) of § 6.342 are revoked, and §§ 6.157 and 6.357 are added as set out below.

§ 6.157 *Federal Home Loan Bank Board.* (a) One Secretary, Federal Home Loan Bank Board.

(b) One Director, Division of Examinations.

(c) All temporary field positions in the Federal Savings and Loan Insurance Corporation concerned with the work of liquidating the assets of closed insured institutions, or the liquidation of loans or the handling of contributions to insured institutions and the purchase of assets therefrom, and all temporary field positions of the Federal Savings and Loan Insurance Corporation the work of which is concerned with paying the depositors of closed insured institutions.

> *This issue is divided into two parts, Part II of which contains a republication of Title 21, Chapter I, of the Code of Federal Regulations.*

§ 6.357 *Federal Home Loan Bank Board.* (a) One Assistant to the Board.

(b) One Director, Federal Home Loan Bank Operations.

(c) One General Counsel.

(d) One Director, Division of Supervision.

(e) One Secretary to the Chairman of the Board.

(f) Two Secretaries to Board Members.

(g) One General Manager, Federal Savings and Loan Insurance Corporation.

(h) One Deputy General Manager, Federal Savings and Loan Insurance Corporation.

(R. S. 1753, sec. 2, 22 Stat. 403; 5 U. S. C. 631, 633; E. O. 10440, 18 F. R. 1823, 3 CFR 1953 Supp.)

UNITED STATES CIVIL SERVICE COMMISSION,
[SEAL] WM. C. HULL,
Executive Assistant.

[F. R. Doc. 55-10149; Filed, Dec. 19, 1955; 8:46 a. m.]

PART 6—EXCEPTIONS FROM THE COMPETITIVE SERVICE

TREASURY DEPARTMENT

Effective upon publication in the FEDERAL REGISTER, paragraph (c) is added to § 6.203 as set out below.

§ 6.203 *Treasury Department.* * * *

(c) Not to exceed two positions of Accountant (Tax Specialist) at grades

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FEDERAL REGISTER

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CFR SUPPLEMENTS
(For use during 1955)

The following Supplement is now available:

General Index ($1.25)

All of the Cumulative Pocket Supplements and revised books of the Code of Federal Regulations (as of January 1, 1955) are now available with the exception of Titles 1–3

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GS-13 and above to serve as specialists on the accounting analysis and treatment of corporation taxes. Employments under this paragraph shall not exceed a period of 18 months in any individual case.

(R. S. 1753, sec. 2, 22 Stat. 403; 5 U. S. C. 631, 633; E. O. 10440, 18 F. R. 1823, 3 CFR 1953 Supp.)

UNITED STATES CIVIL SERVICE COMMISSION,
[SEAL] WM. C. HULL,
Executive Assistant.

[F. R. Doc. 55-10150; Filed, Dec. 19, 1955; 8:46 a. m.]

PART 6—EXCEPTIONS FROM THE COMPETITIVE SERVICE

DEPARTMENT OF STATE; GOVERNMENT PRINTING OFFICE

Effective upon publication in the FEDERAL REGISTER, paragraph (a) of § 6.139 is revoked and paragraph (e) (4) of § 6.302 is amended as set out below.

§ 6.302 *Department of State.* * * *

(e) *Office of the Assistant Secretary for Economic Affairs.* * * *

(4) One Special Assistant to the Assistant Secretary.

(R. S. 1753, sec. 2, 22 Stat. 403; 5 U. S. C. 631, 633; E. O. 10440, 18 F. R. 1823, 3 CFR 1953 Supp.)

UNITED STATES CIVIL SERVICE COMMISSION,
[SEAL] WM. C. HULL,
Executive Assistant.

[F. R. Doc. 55-10152; Filed, Dec. 19, 1955; 8:47 a. m.]

PART 37—GROUP LIFE INSURANCE

CESSATION AND CONVERSION OF INSURANCE COVERAGE

Section 37.5 (f) is amended as set out below.

§ 37.5 *Cessation and conversion of insurance coverage.* * * *

(f) The insurance of an insured employee who enters on active duty in or with the Army, Navy, Air Force, Marine Corps, or Coast Guard of the United States shall cease, subject to a 31-day extension of life insurance coverage, on the day preceding his entrance on such active duty. For this purpose, the employee is considered as performing active duty only if he enters or is called to active military service for a specified term or an indefinite period which is expected to exceed 15 days and is subject to control by military authority for full-time active military service.

(Sec. 11, 68 Stat. 742; 5 U. S. C. 2100)

UNITED STATES CIVIL SERVICE COMMISSION,
[SEAL] WM. C. HULL,
Executive Assistant.

[F. R. Doc. 55-10153; Filed, Dec. 19, 1955; 8:47 a. m.]

TITLE 7—AGRICULTURE

Chapter IX—Agricultural Marketing Service (Marketing Agreements and Orders), Department of Agriculture

PART 914—NAVEL ORANGES GROWN IN ARIZONA AND DESIGNATED PART OF CALIFORNIA

EXPENSES AND FIXING OF RATE OF ASSESSMENT FOR 1955–56 FISCAL YEAR

On November 23, 1955, notice of proposed rule making was published in the FEDERAL REGISTER (20 F. R. 8640) regarding the expenses and rate of assessment for the 1955–56 fiscal year under Marketing Agreement No. 117, as amended, and Order No. 14, as amended (19 F. R. 2941) regulating the handling of Navel oranges grown in Arizona and designated part of California, effective September 22, 1953, under the applicable provisions of The Agricultural Marketing Agreement Act of 1937, as amended (7 U. S. C. 601 et seq.). After consideration of all relevant matters presented, including the proposals set forth in the aforesaid notice which were submitted by the Navel Orange Administrative Committee (established pursuant to the marketing agreement and order), it is hereby found and determined that:

§ 914.203 *Expenses and rate of assessment for the 1955–56 fiscal year.* (a) The expenses necessary to be incurred by the Navel Orange Administrative Committee, established pursuant to the provisions of the aforesaid marketing agreement and order, for its maintenance and functioning during the period November 1, 1955, through October 31, 1956, will amount to $156,832.83; and the rate of assessment to be paid by each handler who first handles oranges shall be seven and one-half mills ($0.0075) per carton of oranges handled by such handler as the first handler thereof during the 1955–56 fiscal year. Such rate of assessment is hereby fixed as each such handler's pro rata share of the aforesaid expenses.

It is hereby further found that it is impracticable and contrary to the public interest to postpone the effective time hereof until 30 days after publication in the FEDERAL REGISTER (60 Stat. 237; 5 U. S. C. 1001 et seq.) in that (1) in accordance with the provisions of said marketing agreement and order, the rate of assessment is applicable to all fresh oranges handled during the aforesaid fiscal year; (2) shipments of Navel oranges are now being made; (3) the provisions hereof do not impose any obligations on a handler until such handler handles Navel oranges; and (4) it is essential that the specification of the assessment rate be issued immediately so that the aforesaid assessments may be collected and thereby enable the Navel Orange Administrative Committee to perform its duties and functions in accordance with said marketing agreement and order.

As used in this section, "handle," "handler," "oranges," and "fiscal year" shall have the same meaning as is given to each such term in said amended marketing agreement and order; and "carton" shall mean the standard one-half orange, grapefruit, or lemon box set forth as standard container number 58 in section 828.83, as amended, of the Agricultural Code of California.

(Sec. 5, 49 Stat. 753, as amended; 7 U. S. C. 608c)

Dated: December 15, 1955.

[SEAL] ROY W. LENNARTSON,
Deputy Administrator.

[F. R. Doc. 55-10188; Filed, Dec. 19, 1955; 8:53 a. m.]

TITLE 16—COMMERCIAL PRACTICES

Chapter I—Federal Trade Commission

[Docket 6319]

PART 13—DIGEST OF CEASE AND DESIST ORDERS

ADMIRAL CORP.

Subpart—*Advertising falsely or misleadingly:* § 13.20 *Comparative data or merits;* § 13.230 *Size or weight.* Subpart—*Misrepresenting oneself and goods*—goods: § 13.1575 *Comparative data or merits;* § 13.1743 *Size or weight.*[1]

(Sec. 6, 38 Stat. 721; 15 U. S. C. 46. Interpret or apply sec. 5, 38 Stat. 719, as amended; 15 U. S. C. 45) [Cease and desist order, Admiral Corporation, Chicago, Ill., Docket 6319, December 3, 1955]

This proceeding was heard by Earl J. Kolb, hearing examiner, upon the complaint of the Commission—which charged a corporate manufacturer of television sets with representing falsely by radio and television broadcasts, advertisements in magazines, newspapers, etc., and advertising material furnished to its distributors, that the screen area of its television sets which were equipped with its Giant 21" picture tube was 20 percent larger than that of its competitors' television sets likewise equipped—and an agreement between the parties providing for the entry of a consent order.

Upon this basis, the hearing examiner made his initial decision and order to cease and desist, which by the Commission's order of December 2, 1955, became, on December 3, 1955, the "Decision of the Commission".

The order to cease and desist is as follows:

It is ordered, That respondent, Admiral Corporation, a corporation, and its officers, agents, representatives, and employees, directly or through any corporate or other device, in connection with the offering for sale, sale, or distribution of television sets in commerce, do forthwith cease and desist from: Misrepresenting directly or by implication the screen area of its television sets as compared with the screen area of its competitors' television sets.

By said "Decision of the Commission", report of compliance was required as follows:

---

[1] New.

It is ordered, That the respondent herein shall within sixty (60) days after service upon it of this order, file with the Commission a report in writing setting forth in detail the manner and form in which it has complied with the order to cease and desist.

Issued: December 2, 1955.

By the Commission.

[SEAL] ROBERT M. PARRISH,
Secretary.

[F. R. Doc. 55-10140; Filed, Dec. 19, 1955; 8:45 a. m.]

TITLE 20—EMPLOYEES' BENEFITS

Chapter III—Bureau of Old-Age and Survivors Insurance, Social Security Administration, Department of Health, Education, and Welfare

[Reg. 1, Further Amended]

PART 401—DISCLOSURE OF OFFICIAL RECORDS AND INFORMATION

ENFORCEMENT OF IMMIGRATION AND NATIONALITY ACT

On October 5, 1955, there was published in the FEDERAL REGISTER (20 F. R. 7398) a notice of proposed rule making incorporating the requirements of section 290 (c) of the Immigration and Nationality Act into a proposed amendment to Social Security Administration Regulation No. 1, as amended (20 CFR 401.1 et seq.). Interested persons were thereby given opportunity to present their data, views and arguments relative to such proposed amendment within 30 days from the date of such publication.

Expressions of views and objections to the proposed amendment have been received pursuant to this notice, and due consideration has been given them. The proposed amendment, however, is based upon the provision of section 290 (c) of the Immigration and Nationality Act which requires the Secretary of Health, Education, and Welfare to disclose certain information, and merely serves the purpose of incorporating the statutory requirement into the regulation so that the regulation will fully set forth all circumstances under which information contained in old-age and survivors insurance records is released. Consequently, it is decided that the regulation shall be amended substantially in accordance with the notice of proposed rule making.

Section 401.3 of Regulation No. 1, as amended (20 CFR 401.3), is, accordingly, further amended by adding thereto a new paragraph (p) reading:

§ 401.3 *Information which may be disclosed and to whom.* Disclosure of any such file, record, report or other paper, or information, is hereby authorized in the following cases and for the following purposes:

* * * * *

(p) Pursuant to the provisions of section 290 (c) of the Immigration and Nationality Act, to any officer or employee of the Department of Justice of the United States lawfully charged with the administration of title II of such act available information required to be furnished by such section, for the purpose of such administration only, upon written request of the Attorney General of the United States or of an official of the Department of Justice duly authorized by him to make such request.

(Secs. 205, 1102, 49 Stat. 624, 647 as amended; 42 U. S. C. 405, 1302. Interprets or applies sec. 1106, 53 Stat. 1398, as amended; 42 U. S. C. 1306)

[SEAL] CHARLES I. SCHOTTLAND,
Commissioner of Social Security.

Approved: December 14, 1955.

M. B. FOLSOM,
Secretary of Health, Education, and Welfare.

[F. R. Doc. 55-10155; Filed, Dec. 19, 1955; 8:47 a. m.]

TITLE 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

REPUBLICATION OF REGULATIONS

CROSS REFERENCE: For republication of the regulations of the Food and Drug Administration, see Part II of this issue.

Chapter II—Bureau of Narcotics, Department of the Treasury

REDESIGNATION OF PARTS

EDITORIAL NOTE: Parts 201, 202, 203, 204, and 205 of this chapter are redesignated Parts 301, 302, 303, 304, and 305, respectively.

TITLE 38—PENSIONS, BONUSES, AND VETERANS' RELIEF

Chapter I—Veterans Administration

PART 14—LEGAL SERVICES, GENERAL COUNSEL

MISCELLANEOUS AMENDMENTS

1. Section 14.627 is revised to read as follows:

§ 14.627 *Accredited representatives.* Recognized organizations shall file with the Veterans Administration on the prescribed form furnished by the Veterans Administration (VA Form 2-21, Recommendation for Accreditation of Representative of an Organization), the name of any person whom they desire recognized as accredited representative thereof. In recommending a person for recognition as a representative, the organization, through its appropriate officer, shall certify to the following: (1) That the designee is a citizen of the United States, of good character and reputation, that he is qualified by ability and experience to present claims, that he is a member of such organization in good standing, or a full-time, paid employee thereof; and that the major portion of his time will be devoted to the preparation or presentation of claims for that organization or other organizations to which he may be accredited or that he is a national officer of the organization requesting accreditation; (2) whether accredited to any other recognized organizations, and, if so, the name or names thereof; (3) that he is not now employed in any civil or military department or agency of the United States and was or was not so employed within 2 years next preceding the date of recommendation for accreditation; (4) if a veteran, the nature of his discharge or separation from the active service. Recommendations for accreditation of representatives of national service organizations will be accepted only if approved by the national certifying officer of such organization; those of State organizations only if approved by the director or higher officer of the organization.

(a) The recommendation for accreditation (VA Form 2-21) executed by a national organization or by a recognized State organization will be filed with the Office of the General Counsel. A recommendation received in Central Office may be sent to the appropriate regional office, if necessary, to secure sufficient facts to justify a determination whether the designee is qualified. The report of the Chief Attorney, including the recommendation, if any, of the Manager, together with VA Form 2-21 will be transmitted to the General Counsel, who will approve or disapprove the recommendation. If the designee is approved, FL 2-3, Notice to Designee of Recognition, will be issued by the General Counsel.

(b) Letters of recognition (FL 2-3) or card issued by the General Counsel (VA Form 2-3192, Service Organization Representative Identification Card) will constitute authorization for the recognition of accredited representatives designated therein, in all offices (including hospitals and domiciliaries) of the Veterans Administration. Record will be maintained in the office of the General Counsel of all recognitions issued.

(c) Recognition of an accredited representative will be canceled at the request of the organization. A manager may suspend recognition in any case for cause, sending a report to Central Office, attention of the General Counsel, for final determination.

(d) An information bulletin will be issued monthly by the office of the General Counsel listing all new accreditations and cancellations. This will constitute notice to all concerned on this subject.

2. In § 14.629 paragraphs (a), (b), and (d) are amended to read as follows:

§ 14.629 *Recognition of attorneys and agents.* (a) Claim agents will be granted recognition and certified by the office of the General Counsel upon satisfactory evidence of qualification, including good reputation and knowledge of applicable law and procedure. Upon presentation to the General Counsel of a properly executed application on the form prescribed by the Administrator, VA Form 3187, Application for recognition as Agent, any competent person of good moral character and of good repute who is a citizen of the United States, or who has declared his intention to become such a citizen, and who is not engaged in the practice of law may be recognized as an agent to represent claimants before the Veterans Administration, if his recognition is not precluded by any statutory or regulatory provision and he has never been convicted, whether on trial or plea, of a serious penal offense, or of any violation of any penal provisions respecting fees. Applicants for recognition as agents may be required to prove their fitness to render substantial service by undergoing a written examination testing their knowledge of the laws administered by the Veterans Administration and regulations promulgated thereunder.

(b) Recognition of attorneys may be granted by a chief Attorney or by the General Counsel. Any member in good standing of the bar of a State, territory, or possession of the United States, or of the bar of the District of Columbia, wherein he resides or maintains a law office, who is a citizen of the United States or who has declared his intention to become such a citizen, may apply for recognition as attorney on VA Form 2–3186, Application for Recognition as Attorney. Such attorney will be presumed to have such knowledge of the law and regulations as to qualify him to render substantial service. If his recognition is not precluded by any statutory or regulatory provision, and he has never been convicted, whether on trial or plea, of a serious penal offense, or of any violation of any penal provisions respecting fees, his application will be approved and he will be notified by letter. Any duly recognized attorney will be accorded recognition in any case by Central Office or by any other office of the Veterans Administration, including hospitals and domiciliaries, to which he presents a duly certified or attested copy of his notification of recognition as attorney or VA Form 2–3192a, Identification Card, together with the original or exemplified copy of power of attorney. (See § 14.639 as to recognition in individual cases.) VA Form 2–3192a, Identification Card, will be issued only by the General Counsel.

* * * * *

(d) Any cause considered sufficient to reject the application of an attorney or agent or to cancel recognition previously granted will be reported by the Chief Attorney to the General Counsel for final determination. Recognition shall be canceled automatically if an attorney or agent is convicted of charging illegal fees contrary to the provisions of the Federal Statutes (38 U. S. C. 101–103, 551, or similar provision). There shall also be applied the provisions of section 6 (a), Public Law 404, 79th Congress (Administrative Procedure Act), (5 U. S. C. 1005).

3. Sections 14.631 and 14.633 are revoked:

§ 14.631 *Knowledge of laws.* [Revoked.]

§ 14.633 *Agents; requirements for recognition.* [Revoked.]

4. Section 14.634 is revised to read as follows:

§ 14.634 *Recognition of attorneys by field stations.* When the Chief Attorney approves an application for recognition as an attorney, he will notify the attorney by letter and inform him that VA Form 2–3192a, Identification Card, will be issued by the General Counsel. The approved application will be retained in the files of the approving office. A 3 x 5 card will be prepared showing the attorney's name, address, and date of recognition. A copy of this card will be forwarded to the office of the General Counsel for record and issuance of VA Form 2–3192a, Identification Card, and to any other office in which the attorney requests that his recognition be recorded. When an attorney has been recognized by the General Counsel, no copy of the 3 x 5 card will be sent to any office unless the attorney specifically requests that his recognition be recorded in a certain office.

(Sec. 5, 43 Stat. 608, as amended, sec. 2, 46 Stat. 1016, sec. 7, 48 Stat. 9; 38 U. S. C. 11a, 426, 707. Interpret or apply secs. 200–203, 49 Stat. 2031, as amended, 2032; 38 U. S. C. 101–104)

This regulation is effective December 20, 1955.

[SEAL] J. C. PALMER,
Assistant Deputy Administrator.

[F. R. Doc. 55–10161; Filed, Dec. 19, 1955; 8:49 a. m.]

PART 17—MEDICAL

MISCELLANEOUS AMENDMENTS

1. Section 17.30 is revised to read as follows:

§ 17.30 *Refusal of treatment by unnecessarily breaking appointments.* A patient under outpatient medical treatment who breaks an appointment without a reasonable excuse for such action, will be informed that a repetition of the offense will be deemed to be a refusal of Government treatment. If such patient breaks a second appointment, without at least 24 hours' notice, or a reasonable excuse, it will be deemed that he has refused Government treatment. Thereafter no further treatment will be furnished until he has made a specific formal application therefor and has satisfactorily evinced a willingness to accept Government treatment and to cooperate with the Government agency providing the treatment, by keeping his appointments, or by giving at least 24 hours' notice where an appointment must necessarily be broken. Where an appointment is broken without notice and satisfactory reasons are shown for the breaking of the appointment, and it is also satisfactorily shown that circumstances attending the breaking of the appointment were such that notice could not be given, the patient will not be deemed to have refused treatment. Nothing in this section will be construed to prevent a patient from receiving the benefit of treatment for an emergency condition that may arise during the time when he has been determined to be "Not entitled to treatment" as a result of refusal.

2. In § 17.60, that portion of paragraph (a) preceding subparagraph (1) is amended to read as follows:

§ 17.60 *Outpatient treatment.* (a) Outpatient treatment, medical or dental, including necessary medicines, prosthetic appliances, and other supplies, may be rendered to the following applicants under the conditions stated, except that applicants for dental treatment as defined in subparagraphs (1), (3), (4), and (9), of this paragraph, must also meet the applicable provisions of § 17.123:

* * * * *

3. In § 17.120, paragraph (a) is amended to read as follows:

§ 17.120 *Authorization of dental examinations.* * * *

(a) Those having a dental disability adjudicated as incurred or aggravated in military or naval service in war or peacetime, or those requiring examination to determine whether the dental disability is service-connected. The word "peacetime" as used in this paragraph does not include service on or after June 27, 1950, and prior to February 1, 1955.

* * * * *

4. Sections 17.123, 17.124, and 17.129 are revised to read as follows:

§ 17.123 *Authorization of outpatient dental treatment.* Outpatient dental treatment may be authorized by the chief, dental service, or his professional designee, for beneficiaries defined in § 17.60 (a) (1) to (5), inclusive, (8), (9), and (b), to the extent prescribed and in accordance with the applicable classification and provisions set forth in this section:

(a) *Class I.* Those having a service-connected compensable dental disability or condition, may be authorized any dental treatment indicated as reasonably necessary to maintain oral health and masticatory function. There is no time limitation for making application for treatment and no restriction as to the number of repeat episodes of treatment.

(b) *Class II.* Those having a service-connected noncompensable dental condition or disability shown to have been in existence at time of discharge or release from active service may be authorized any treatment indicated as reasonably necessary for the one-time correction of the service-connected noncompensable dental disability or condition, but only if application for treatment is made within 1 year after discharge or release, or by December 31, 1954. When the services rendered on a one-time basis, as provided in this class, are found unacceptable within the limitations of good professional standards, such additional services may be afforded as are required to complete professionally acceptable treatment. The foregoing limitations in this class II as to existence of disability at time of separation from service, time of filing claim, and one-time completion of treatment are not applicable to Classes II (a) and (b).

(c) *Class II (a).* Those having a service-connected noncompensable dental condition or disability adjudicated as resulting from combat wounds or service trauma may be authorized any treatment indicated as reasonably necessary for the correction of such service-connected noncompensable condition or disability.

(d) *Class II (b).* Those having a service-connected noncompensable dental condition or disability and former prisoner of war status may be authorized any treatment indicated as reasonably necessary for the correction of such service-connected dental condition or disability.

(e) *Class III.* Those having a dental condition not service connected but professionally determined to be aggravating disability from an associated service-connected condition or disability may be authorized dental treatment for only those dental conditions which, in sound professional judgment, are having a direct and material detrimental effect upon the associated basic condition or disability.

(f) *No Class IV.*

(g) *Class V.* Those pursuing a course of vocational training authorized under Public Law 16, 78th Congress, as amended and extended, may be authorized dental treatment indicated as reasonably necessary to prevent the interruption of an authorized course of vocational training.

(h) *Class VI.* Those who served in the active military or naval forces during the Spanish-American War, Philippine Insurrection, or Boxer Rebellion, may be authorized any dental treatment indicated as reasonably necessary to maintain oral health and masticatory function. There is no time limit for making application for treatment and no restriction as to the number of repeat episodes of treatment.

§ 17.124 *Emergency dental treatment.* Emergency dental treatment may be furnished persons hospitalized or receiving domiciliary care pursuant to the provisions of §§ 17.35, 17.45 to 17.47, inclusive; Veterans Administration employees; and persons defined in § 17.60, when eligibility therefor has been established or there is prima facie evidence of eligibility. Emergency dental treatment may be furnished for humanitarian reasons in Veterans Administration clinics for persons not otherwise eligible. However, in providing emergency dental treatment for humanitarian reasons, a rigid interpretation of emergency dental treatment as defined in this section will be followed and charges at prescribed rates will be made for the services rendered. Emergency dental treatment will be restricted to the alleviation of pain or extreme discomfort, or the adequate remediation of a dental condition which is determined to be immediately endangering the life or health of the individual. The rendering of such emergency treatment will not, in itself, entitle the applicant to further dental treatment that may be indicated unless and until eligibility for such continuous treatment is duly determined. Emergency dental treatment rendered on a fee basis may only be authorized if eligibility therefor has been established under the provisions of § 17.123; if Veterans Administration clinical facilities were not feasibly available; and if the treatment rendered on an emergency basis is promptly reported.

§ 17.129 *Dental services for hospital patients and domiciled members.* Persons hospitalized or domiciled pursuant to the provisions of §§ 17.46 and 17.47, will be furnished such dental services as are professionally determined necessary to the patients' or members' overall hospital or domiciliary care.

5. Section 17.135 *Replacement of dental prosthesis* is revoked.

(Sec. 5, 43 Stat. 608, as amended, sec. 2, 46 Stat. 1016, sec. 7, 48 Stat. 9; 38 U. S. C. 11a, 426, 707. Interpret or apply secs. 1, 6, 48 Stat. 9, 301, 53 Stat. 652, as amended; 38 U. S. C. 706, 706a)

This regulation is effective December 20, 1955.

[SEAL] J. C. PALMER,
Assistant Deputy Administrator.

[F. R. Doc. 55-10160; Filed, Dec. 19, 1955; 8:49 a. m.]

TITLE 43—PUBLIC LANDS: INTERIOR

Chapter I—Bureau of Land Management, Department of the Interior

Appendix—Public Land Orders

[Public Land Order 1261]

[Misc. 29637]

UTAH

WITHDRAWING PUBLIC LANDS FOR USE OF GEOLOGICAL SURVEY AS SEDIMENT TESTING LABORATORY SITE

By virtue of the authority vested in the President and pursuant to Executive Order No. 10355 of May 26, 1952, it is ordered as follows:

Subject to valid existing rights, the following-described public lands in Utah are hereby withdrawn from all forms of appropriation under the public-land laws, including the mining and mineral-leasing laws, and reserved under the jurisdiction of the Department of the Interior for use of the Geological Survey as a site for a sediment testing laboratory:

SALT LAKE MERIDIAN

T. 34 S., R. 13 E.,
Sec. 35, S½S½NE¼NE¼;
Sec. 36, lot 1.

The areas described aggregate 44.99 acres.

The use of the lands by the Geological Survey shall be subject to existing withdrawals for power purposes, and to the condition that should the lands be required for power purposes, any structures placed thereon which interfere therewith will be removed by the Geological Survey.

This order shall take precedence over but not otherwise affect the Departmental order of May 7, 1935, establishing Utah Grazing District No. 5.

WESLEY A. D'EWART,
Assistant Secretary of the Interior.

DECEMBER 14, 1955.

[F. R. Doc. 55-10139; Filed, Dec. 19, 1955; 8:45 a. m.]

TITLE 39—POSTAL SERVICE

Chapter I—Post Office Department

PART 41—SERVICE IN POST OFFICES

POST OFFICE BOXES

In § 41.3 *Post office boxes* make the following changes:

1. Amend paragraph (c) to read as follows:

(c) *Rental rates*—(1) *Post office.* Box rent rates are based on the gross receipts of the office for the calendar year.

(2) *Rates.* No change in existing rates will be made by postmasters without authority from the Bureau of Finance, Division of Postal Funds.

(3) *Schedule.*

Gross receipts of post office	Rate per quarter						
	Call boxes—Size No.		Lock boxes and drawers—Size No.				
	1	2	1	2	3	4	5
	Cubic inch capacity		Cubic inch capacity				
	To 225	225 to 500	To 225	225 to—	500 to—	900 to—	3,000 and over
To $1,500	$0.15	$0.20	$0.35	$0.50	$0.65	$0.90	$1.10
$1,500 to	.20	.30	.50	.65	.90	1.10	1.50
$8,000 to	.35	.50	.75	1.00	1.35	2.00	2.75
$40,000 to	.65	.90	1.10	1.50	2.25	3.00	4.50
$100,000 to	.90	1.10	1.50	2.25	3.00	4.50	6.00
$300,000 to	1.10	1.50	2.25	3.00	4.50	6.00	7.50
$1,000,000 to	1.50	2.25	3.00	4.50	6.00	7.50	9.00
$5,000,000 to	2.25	3.00	4.50	6.00	7.50	9.00	10.50
$15,000,000 and over	3.00	4.50	6.00	7.50	9.00	10.50	12.00

2. Amend paragraph (f) to read as follows:

(f) *Keys*—(1) *Regular.* A patron renting a key-lock box must be supplied with one or two keys, according to his needs. Renters of lock boxes are not permitted to use any keys except those issued through the post office.

(2) *Additional.* Keys in excess of two may be secured by a patron upon completion of Form 1094 (application for additional keys to post office box) and payment of a 50 cents fee for each key.

(3) *Duplicate.* Duplicates of lost keys may be secured by payment of a 50 cents fee for each key.

(4) *Fees not refundable.* Fees for duplicate and additional keys are not refundable.

(5) *Worn and broken.* Worn or broken keys shall be replaced without charge if the damaged key is surrendered.

(6) *Return.* All keys must be returned when the box is surrendered. If the patron has lost a regular key, he must pay a fee of 50 cents for each missing key.

(R. S. 161, 396; secs. 304, 309, 42 Stat. 24, 25; 5 U. S. C. 22, 369)

[SEAL] ABE MCGREGOR GOFF,
The Solicitor.

[F. R. Doc. 55-10142; Filed, Dec. 19, 1955; 8:45 a. m.]

TITLE 45—PUBLIC WELFARE

Chapter V—Foreign Claims Settlement Commission of the United States

Subchapter C—Receipt, Administration and Payment of Claims Under the International Claims Settlement Act of 1949, as Amended

PART 531—FILING OF CLAIMS AND PROCEDURES THEREFOR

PRESETTLEMENT CONFERENCE

Section 531.7 is added to read as follows:

§ 531.7 *Presettlement conference.* The Commission on its own initiative or upon the application of a claimant for good cause shown, may direct that a presettlement conference be held with respect to any issue involved in a claim.

This addition shall become effective as of the date of filing with the FEDERAL REGISTER.

(Sec. 3, 64 Stat. 13, as amended; 22 U. S. C. 1622)

WHITNEY GILLILAND,
Chairman, Foreign Claims Settlement Commission of the United States.

[F. R. Doc. 55-10141; Filed, Dec. 19, 1955; 8:45 a. m.]

TITLE 47—TELECOMMUNICATION

Chapter I—Federal Communications Commission

[Rules Amdt. 18-9]

PART 18—INDUSTRIAL, SCIENTIFIC, AND MEDICAL SERVICE

MISCELLANEOUS AMENDMENTS

In the matter of amendment of Part 18 of the Commission's rules and regulations governing the Industrial, Scientific, and Medical Service.

The Commission's order in the above-entitled matter, adopted September 12, 1955 (FCC 55-929), published in the FEDERAL REGISTER September 16, 1955, at page 6927, is corrected in the following respect: In § 18.14 (b) (1) change 35 percent to 70 percent.

Released: December 14, 1955.

FEDERAL COMMUNICATIONS
COMMISSION,
[SEAL] MARY JANE MORRIS,
Secretary.

(Sec. 4, 48 Stat. 1066, as amended; 47 U. S. C. 154. Inteprets or applies sec. 303, 48 Stat. 1082, as amended; 47 U. S. C. 303)

[F. R. Doc. 55-10162; Filed, Dec. 19, 1955; 8:49 a. m.]

PROPOSED RULE MAKING

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[7 CFR Part 908]

[Docket No. AO-243-A1]

MILK IN CENTRAL ARKANSAS MARKETING AREA

NOTICE OF RECOMMENDED DECISION AND OPPORTUNITY TO FILE WRITTEN EXCEPTIONS THERETO WITH RESPECT TO PROPOSED MARKETING AGREEMENT AND PROPOSED AMENDMENTS TO ORDER

Pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U. S. C. 601 et seq.) and the applicable rules of practice and procedure, as amended, governing proceedings to formulate marketing agreements and marketing orders (7 CFR Part 900), notice is hereby given of the filing with the Hearing Clerk of the recommended decision of the Deputy Administrator, Agricultural Marketing Service, United States Department of Agriculture, with respect to proposed amendments to the tentative marketing agreement and to the order, regulating the handling of milk in the Central Arkansas marketing area.

Interested parties may file written exceptions to the decision with the Hearing Clerk, United States Department of Agriculture, Washington 25, D. C., not later than the close of business on the 5th day after publication of this decision in the FEDERAL REGISTER. Exceptions should be filed in quadruplicate.

Preliminary statement. The hearing on the record of which the proposed amendment to the tentative marketing agreement and to the order was formulated was conducted at Little Rock, Arkansas, on November 22, 1955, pursuant to notice thereof which was issued on November 15, 1955 (20 F. R. 8547).

The material issues of the hearing relate to:

(1) The pricing of Class I milk; and

(2) The need for emergency action with respect to Issue No. 1.

Findings and conclusions. The order should be amended to correlate Class I price changes in the Central Arkansas marketing area with those resulting under Order No. 52 regulating the handling of milk in the Memphis, Tennessee, marketing area.

The pricing provisions of the Central Arkansas Order No. 8 became effective December 1, 1955. Class I prices under the Central Arkansas and Memphis orders are established by adding identical differentials to basic prices for manufacturing milk. The monthly price resulting from the price formula under the Memphis order, however, is subject to an adjustment based on the relationship of Class I sales to receipts of producer milk under that order. During the months of July through November, 1955, an average of 19 cents was added to the Class I price by the operation of this supply-demand adjustment. No adjustment resulted in prices for the months of May and June or for December of this year. Thus, the Class I prices under the two orders are the same for the month of December.

Starting in April of 1955 and continuing until the pricing provisions of the Central Arkansas order became effective (December 1, 1955), the Central Arkansas Milk Producers Association had an arrangement with the principal handlers of the Central Arkansas marketing area to furnish their total milk requirements at the class prices prevailing under the Memphis order. Thus, in effect the order continues the pricing arrangement negotiated by producers and handlers prior to the effective date of the order.

Under the association's full supply agreement with the handlers, it was necessary for the association to import milk from outside sources starting in July. During the months of shortest supply namely September and October, 1.6 and 2.1 million pounds of milk, respectively, were furnished from outside sources.

The Central Arkansas Milk Producer's proposal would provide for an automatic adjustment of the Class I price of the Central Arkansas order based upon the supply-demand adjustment provided in the Class I pricing provisions of the Memphis order.

On the basis of the present deficit condition of the market and increasing costs of production, producers contended at the hearing that the Class I price under the Central Arkansas order should be increased 20 to 30 cents per hundredweight. They further argued that this should be accomplished either through an increase in the Class I price differentials or through a supply-demand provision identical to that contained in the Memphis order but by the application of the receipts and utilization of milk in the Central Arkansas marketing area.

Neither this record nor the promulgation hearing record contains data which fully reflect the receipts and sales of fluid milk in the Central Arkansas area. It is not possible to develop a "normal" or "standard" relationship of sales to receipts. The evidence does not indicate that the adoption of the Memphis supply-demand relationship in the Central Arkansas order is justified. Furthermore, it is not possible to appraise the production responses which can be expected under an order with the present pricing arrangement.

It was previously concluded in the Secretary's decision of October 7, 1955, (20 F. R. 7669) with respect to the proposed order for the Central Arkansas marketing area, that because the previous price and supply history of the market could not be fully relied upon, it was not possible to arrive at an appropriate Class I price for this area on the basis of local experience alone. It was further concluded, that because of the large degree of sales competition, the location of the Central Arkansas market in relation to the Memphis market and the relationship of both markets to other supply and sales areas, the stated Class I differentials in the Memphis and the Central Arkansas orders should be the same. The record evidence of the price and supply experience in this market since the promulgation hearing was held shows an even closer relationship between these two markets. Class I prices, as previously indicated heretofore, have been the same during the past several months. It is concluded, therefore, that for the immediate future Class I prices in the two markets should be the same.

This should be accomplished by providing that through March of 1957 the Class I price for the Central Arkansas marketing area shall be the same as the Class I price resulting under the Memphis Order No. 18 including any adjustments resulting from the supply-demand adjustment of that order. Sufficient experience and marketing data will be available by March of 1957 to provide a basis for a more complete appraisal of the pricing arrangement for the Central Arkansas marketing area.

In view of the fact that Class I prices are identical under both the Memphis and Central Arkansas orders for the month of December 1955 and no substantial differences in prices between the two markets, which would be avoided through the attached decision, are indicated in the near future, there appears to be no need for emergency action as requested on the record of hearing.

General findings. (a) The proposed marketing agreement and the order as hereby proposed to be amended, and all of the terms and conditions thereof will tend to effectuate the declared policy of the act;

(b) The parity prices of milk as determined pursuant to section 2 of the act are not reasonable in view of the price of feeds, available supplies of feeds and other economic conditions which affect market supply and demand for milk in the marketing area, and the minimum prices specified in the proposed marketing agreement and the order, as hereby proposed to be amended, are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk and be in the public interest; and

(c) The proposed order, as hereby proposed to be amended, will regulate the handling of milk in the same manner as and will be applicable only to persons in the respective classes of industrial and commercial activity specified in a marketing agreement upon which a hearing has been held.

Rulings on proposed findings and conclusions. A brief filed on behalf of the producer organization contained proposed findings, conclusions, and arguments with respect to the provisions of the proposed amendment. Every point covered in the brief was carefully considered along with the evidence in the record in making the findings and reaching conclusions hereinbefore set forth. To the extent that the findings and conclusions proposed in the brief are inconsistent with the findings and conclusions contained herein, the request to make such findings or to reach such conclusions is denied on the basis of the facts found and stated in connection with the conclusions in this recommended decision.

Recommended marketing agreement and amendment to the order. The following order, amending the order, is recommended as the detailed and appropriate means by which the foregoing conclusions may be carried out. The proposed marketing agreement is not included in this decision because the regulatory provisions thereof would be identical with those contained in the order, as hereby proposed to be amended.

Delete § 908.51 (a) and substitute therefor the following:

(a) *Class I milk price.* From the effective date hereof through March 1957, the Class I milk price shall be the price for Class I milk established pursuant to Federal Order No. 18, regulating the handling of milk in the Memphis, Tennessee marketing area.

Filed at Washington, D. C., this 15th day of December 1955.

[SEAL] ROY W. LENNARTSON,
Deputy Administrator.

[F. R. Doc. 55-10189; Filed, Dec. 19, 1955; 8:53 a. m.]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 120]

TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

NOTICE OF FILING OF PETITION FOR ESTABLISHMENT OF TOLERANCE FOR RESIDUES OF SODIUM-O-PHENYLPHENATE

Pursuant to the provisions of the Federal Food, Drug, and Cosmetic Act (sec. 408 (d) (1), 68 Stat. 512; 21 U. S. C. 346a (d) (1)), the following notice is issued:

A petition has been filed by The Dow Chemical Company, Midland, Michigan, proposing the establishment of a tolerance of 10 parts per million for residues of sodium-*o*-phenylphenate, determined as orthophenylphenol, in or on citrus fruits.

The analytical method proposed in the petition for determining residues of orthophenylphenol is as follows: An acidified sample of orange peel or pulp is steam distilled. Orthophenylphenol is extracted from the distillate with petroleum ether. The petroleum ether solution obtained is washed with sodium hydroxide, and the orthophenylphenol in the alkaline extract is determined colorimetrically by the 4-aminoantipyrine method.

References:

a. Tompkins, R. G., and Isherwood, F. A.; Analyst, Volume 70, pages 330–333 (1945).

b. Gottlieb, S., and Marsh, P. B.; Industrial and Engineering Chemistry, Anal. Edition, Volume 18, pages 16–19 (1946).

Dated: December 13, 1955.

[SEAL] GEO. P. LARRICK,
Commissioner of Food and Drugs.

[F. R. Doc. 55-10154; Filed, Dec. 19, 1955; 8:47 a. m.]

NOTICES

DEPARTMENT OF THE TREASURY

United States Coast Guard

[CGFR 55-51]

TERMINATION OF APPROVAL OF EQUIPMENT

By virtue of the authority vested in me as Commandant, United States Coast Guard, by Treasury Department Order No. 120, dated July 31, 1950 (15 F. R. 6521), and Treasury Department Order 167-14, dated November 26, 1954 (19 F. R. 8026), and in compliance with the authority cited with each item of equipment, the following approvals of equipment are terminated because (1) the manufacturer is no longer in business; or (2) the manufacturer does not desire to retain the approval; or (3) the item is no longer being manufactured; or (4) the item of equipment no longer complies with present Coast Guard requirements; or (5) the approval has expired. Except for those approvals which have expired, all other terminations of approvals made by this document shall be made effective upon the thirty-first day after the date of publication of this document in the FEDERAL REGISTER. Notwithstanding this termination of approval of any item of equipment as listed in this document, such equipment in service may be continued in use so long as such equipment is in good and serviceable condition.

DAVITS, LIFEBOATS

Termination of Approval No. 160.032/120/0, mechanical davit, Quadrant Type Q30D, approved for maximum working load of 6,000 pounds per set (3,000 pounds per arm) using not less than 6-part falls, identified by general arrangement dwg. No. 2372 dated September 15, 1942, and revised November 10, 1942, submitted by Welin Davit and Boat Division of Continental Copper & Steel Industries, Inc., Perth Amboy, N. J. (Approved FEDERAL REGISTER November 11, 1950. Termination of approval effective November 11, 1955.)

(R. S. 4405, as amended, and 4462, as amended, 46 U. S. C. 375, 416. Interpret or apply R. S. 4417a, as amended, 4426, as amended, 4481, as amended, 4488, as amended, 4491, as amended, secs. 1 and 2, 49 Stat. 1544, as amended, sec. 3, 54 Stat. 346, as amended, and sec. 3 (c), 68 Stat. 676; 46 U. S. C. 391a, 404, 474, 481, 489, 367, 1333, 50 U. S. C. 198; E. O. 10402, 17 F. R. 9917, 3 CFR, 1952 Cum. Supp.; 46 CFR 160.032)

LIFEBOATS

Termination of Approval No. 160.035/267/0, 12.0′ x 4.42′ x 1.92′ steel, square stern, oar-propelled lifeboat, 6-person capacity, identified by construction and arrangement dwg. No. 3334 dated May 26, 1950, and revised September 14, 1950, manufactured by Welin Davit and Boat Division of Continental Copper & Steel Industries, Inc., Perth Amboy, N. J. (Approved FEDERAL REGISTER November 11, 1950. Termination of approval effective November 11, 1955.)

(R. S. 4405, as amended, and 4462, as amended, 46 U. S. C. 375, 416. Interpret or apply R. S. 4417a, as amended, 4426, as amended, 4481, as amended, 4488, as amended, 4491, as amended, 4492, as amended, sec. 11, 35 Stat. 428, as amended, secs. 1 and 2, 49 Stat. 1544, as amended, sec. 3, 54 Stat. 346, as amended, and sec. 3 (c), 68 Stat. 676; 46 U. S. C. 391a, 404, 474, 481, 489, 490, 396, 367, 1333, 50 U. S. C. 198; E. O. 10402, 17 F. R. 9917, 3 CFR, 1952 Supp.; 46 CFR 160.035)

BUOYANT CUSHIONS, KAPOK OR FIBROUS GLASS

Termination of Approval No. 160.048/14/0, special approval for 14″ x 44″ x 2″ rectangular kapok buoyant cushion, 55 oz. kapok, dwg. Nos. A-38, and C-48, dated July 6, 1955, manufactured by The American Pad & Textile Co., Greenfield, Ohio. (Approved FEDERAL REGISTER August 13, 1955.)

Termination of Approval No. 160.048/15/0, special approval for 14″ x 48″ x 2″ rectangular kapok buoyant cushion, 60 oz. kapok, dwg. Nos. A-39, and C-48, dated July 6, 1955, manufactured by The American Pad & Textile Co., Greenfield, Ohio. (Approved FEDERAL REGISTER August 13, 1955.)

Termination of Approval No. 160.048/16/0, special approval for 14″ x 54″ x 2″ rectangular kapok buoyant cushion, 67 oz. kapok, dwg. Nos. A-40, and C-48, dated July 6, 1955, manufactured by The American Pad & Textile Co., Greenfield, Ohio. (Approved FEDERAL REGISTER August 13, 1955.)

(R. S. 4405, as amended, 4462, as amended; 46 U. S. C. 375, 416. Interpret or apply secs. 6, 17, 54 Stat. 164, 166, as amended; 46 U. S. C. 526e, 526p; 46 CFR 160.048)

BOILER, HEATING

Termination of Approval No. 162.003/61/2, size 3824-8C vertical fire tube hot water heating boiler, welded steel plate construction, oil fired, 30 pounds per square inch maximum pressure, dwg. No. H-110-5, Rev. 3, dated January 3, 1951, manufactured by Way-Wolff Associates, Inc., 33 Fulton Street, New York 38, N. Y. (Approved FEDERAL REGISTER March 21, 1951.)

Termination of Approval No. 162.003/85/0, size 380-10E vertical fire tube steam or hot water heating boiler, welded steel plate construction, oil fired, 30 pounds per square inch maximum pressure, dwg. No. H-110-2, Rev. 4, dated January 3, 1951, manufactured by Way-Wolff Associates, Inc., 33 Fulton Street, New York 38, N. Y. (Approved FEDERAL REGISTER March 21, 1951.)

Termination of Approval No. 162.003/86/0, size 4536-12E vertical fire tube steam or hot water heating boiler, welded steel plate construction, oil fired, 30 pounds per square inch maximum pressure, dwg. No. H-110-2, Rev. 4, dated January 3, 1951, manufactured by Way-Wolff Associates, Inc., 33 Fulton Street, New York 38, N. Y. (Approved FEDERAL REGISTER March 21, 1951.)

Termination of Approval No. 162.003/87/0, size 6642-14E vertical fire tube steam or hot water heating boiler, welded steel plate construction, oil fired, 30 pounds per square inch maximum pressure, dwg. No. H-110-2, Rev. 4, dated January 3, 1951, manufactured by Way-Wolff Associates, Inc., 33 Fulton Street, New York 38, N. Y. (Approved FEDERAL REGISTER March 21, 1951.)

Termination of approval of hot water heating boilers, copper tube construction, 30 pounds per square inch maximum pressure, manual control, dwg. No. 6-1000-A dated August 17, 1950, manufactured by The Heat Exchanger Co., 415 Denny Way, Seattle 9, Wash., for the following model numbers:

Approval No.	Model	Water output B. t. u./hour
162.003/110/0	B-1	120,000
162.003/111/0	B-2	190,000
162.003/112/0	B-7	240,000
162.003/113/0	B-10	390,000
162.003/114/0	SH	90,000

(Approved FEDERAL REGISTER November 11, 1950. Termination of approval effective November 11, 1955.)

(R. S. 4405, 4417a, 4418, 4426, 4433, 4434, 4491, as amended, secs. 1, and 2, 49 Stat. 1544, sec. 3, 54 Stat. 346, as amended, and sec. 3 (c), 68 Stat. 676; 46 U. S. C. 367, 375, 391a, 392, 404, 411, 412, 489, 1333, 50 U. S. C. 198; 46 CFR Part 52)

VALVES, RELIEF, HOT WATER HEATING BOILERS

Termination of Approval No. 162.013/6/0, Type No. 499 relief valve for hot water heating boilers, maximum set pressure 30 p. s. i., relieving capacity, 500,000 B. t. u. per hour, dwg. No. RA-13 dated July 13, 1950, inlet size ¾″, manufactured by Bell & Gossett Company, 8200 North Austin Avenue, Morton Grove, Ill. (Approved FEDERAL REGISTER February 17, 1951.)

Termination of Approval No. 162.013/7/0, Type No. 1000 relief valve for hot water heating boilers, maximum set pressure 30 p. s. i., relieving capacity 1,000,000 B. t. u. per hour, dwg. No. RSA-1000 dated March 30, 1950, inlet size 1½″, manufactured by Bell & Gossett Company, 8200 North Austin Avenue, Morton Grove, Ill. (Approved FEDERAL REGISTER February 12, 1951.)

(R. S. 4405, as amended, and 4462, as amended, 46 U. S. C. 375, 416. Interpret or apply R. S. 4417a, as amended, 4418, as amended, 4426, as amended, 4433, as amended, 4491, as amended, secs. 1 and 2, 49 Stat. 1544, as amended, sec. 3, 54 Stat. 346, as amended, and sec. 3 (c), 68 Stat. 676; 46 U. S. C. 391a, 392, 404, 411, 489, 367, 1333, 50 U. S. C. 198; E. O. 10402, 17 F. R. 9917, 3 CFR, 1952 Supp.; 46 CFR 162.013)

APPLIANCES, LIQUEFIED PETROLEUM GAS CONSUMING

Termination of Approval No. 162.020/31/0, Magic Chef gas deep fat fryer, Model No. 314-72, approved by the American Gas Association, Inc., under Certificate No. 13-9-1.011 for liquefied petroleum gas service, manufactured by American Stove Co., 4931 Daggett Avenue, St. Louis 10, Mo. (Approved FEDERAL REGISTER November 11, 1950. Termination of approval effective November 11, 1955.)

Termination of Approval No. 162.020/32/0, Magic Chef gas deep fat fryer, Model No. 316-72, approved by the American Gas Association, Inc., under Certificate No. 13-9-1.011 for liquefied petroleum gas service, manufactured by American Stove Co., 4931 Daggett Avenue, St. Louis 10, Mo. (Approved FEDERAL REGISTER November 11, 1950. Termination of approval effective November 11, 1955.)

Termination of Approval No. 162.020/33/0, Magic Chef gas deep fat fryer, Model No. 310-72, approved by the American Gas Association, Inc., under Certificate Nos. 13-9-1.011 and 13-9.1 for liquefied petroleum gas service, manufactured by American Stove Co., 4931 Daggett Avenue, St. Louis 10, Mo. (Approved FEDERAL REGISTER November 11, 1950. Termination of approval effective November 11, 1955.)

Termination of Approval No. 162.020/34/0, Magic Chef gas deep fat fryer, Model No. 312-72, approved by the American Gas Association, Inc., under Certificate Nos. 13-9-1.011 and 13-9.1 for liquefied petroleum gas service, manufactured by American Stove Co., 4931 Daggett Avenue, St. Louis 10, Mo. (Approved FEDERAL REGISTER November 11, 1950. Termination of approval effective November 11, 1955.)

(R. S. 4405, 4417a, 4426, 4491, secs. 1, 2, 49 Stat. 1544, and sec. 2, 54 Stat. 1028, as amended, and sec. 3 (c), 68 Stat. 676; 46 U. S. C. 367, 375, 391a, 404, 463a, 489, 1333, 50 U. S. C. 198; 46 CFR 55.16-10)

Dated: December 13, 1955.

[SEAL] A. C. RICHMOND,
Vice Admiral, U. S. Coast Guard,
Commandant.

[F. R. Doc. 55-10158; Filed, Dec. 19, 1955; 8:48 a. m.]

[CGFR 55-50]

APPROVAL OF EQUIPMENT AND CHANGE IN MANUFACTURER'S ADDRESS

By virtue of the authority vested in me as Commandant, United States Coast Guard, by Treasury Department Order No. 120, dated July 31, 1950 (15 F. R. 6521), and Treasury Department Order 167-14, dated November 26, 1954 (19 F. R. 8026), and in compliance with the authority cited with each item of equipment: *It is ordered*, That:

(a) All the approvals listed in this document which extend approvals previously published in the FEDERAL REGISTER are prescribed and shall be in effect for a period of five years from their respective dates as indicated at the end of each approval, unless sooner canceled or suspended by proper authority; and,

(b) All the other approvals listed in this document (which are not covered by paragraph (a) above) are prescribed and shall be in effect for a period of five years from the date of publication of this document in the FEDERAL REGISTER, unless sooner canceled or suspended by proper authority; and,

(c) The change in the name of the manufacturer of approved equipment shall be made as indicated below.

LIFE PRESERVERS, KAPOK, ADULT AND CHILD (JACKET TYPE) MODELS 2, 3, 5, AND 6

Approval No. 160.002/52/0, Model 2, adult kapok life preserver, U. S. C. G. Specification Subpart 160.002, manufactured by The Safegard Corp., Box 66, Station B, Cincinnati 22, Ohio, for Sears, Roebuck and Co., 925 South Homan Avenue, Chicago 7, Ill.

Approval No. 160.002/53/0, Model 6, child kapok life preserver, U. S. C. G. Specification Subpart 160.002, manufactured by The Safegard Corp., Box 66, Station B, Cincinnati 22, Ohio, for Sears, Roebuck and Co., 925 South Homan Avenue, Chicago 7, Ill.

(R. S. 4405, as amended, and 4462, as amended, 46 U. S. C. 375, 416. Interpret or apply R. S. 4417a, 4426, 4481, 4482, 4488, 4491, 4492, as amended, sec. 11, 35 Stat. 428, secs. 1, 2, 49 Stat. 1544, secs. 6, 17, 54 Stat. 164, 166, and sec. 3, 54 Stat. 346, as amended, and 3 (c), 68 Stat. 676; 46 U. S. C. 391a, 404, 474, 475, 481, 489, 490, 396, 367, 526e, 526p, 1333, 50, U. S. C. 198; E. O. 10402, 17 F. R. 9917, 3 CFR, 1952 Supp.; 46 CFR 160.002)

LIFE PRESERVERS, CORK (JACKET TYPE) MODELS 32 AND 36

Approval No. 160.003/13/0, Model 32, adult cork life preserver, U. S. C. G. Specification Subpart 160.003, manufactured by Noble Products Co., Box 327, Caldwell, Ohio.

Approval No. 160.003/14/0, Model 36, child cork life preserver, U. S. C. G. Specification Subpart 160.003, manufactured by Noble Products Co., Box 327, Caldwell, Ohio.

(R. S. 4405, as amended, and 4462, as amended, 46 U. S. C. 375, 416. Interpret or apply R. S. 4417a, 4426, 4481, 4482, 4488, 4491, 4492, as amended; sec. 11, 35 Stat. 428, secs. 1, 2, 49 Stat. 1544, secs. 6, 17, 54 Stat. 164, 166, and sec. 3, 54 Stat. 346, as amended, and sec. 3, (c), 68 Stat. 676; 46 U. S. C. 391a, 404, 474, 475, 481, 489, 490, 396, 367, 526e, 526p, 1333, 50 U. S. C. 198; E. O. 10402, 17 F. R. 9917, 3 CFR, 1952 Supp.; 46 CFR 160.003)

CLEANING PROCESSES FOR LIFE PRESERVERS

(Where buoyancy fillers are not removed from envelope covers during cleaning process.)

Approval No. 160.006/24/0, Rex cleaning process for kapok life preservers without vinyl covered pad inserts, as outlined in letter of October 1, 1955, from Rex Cleaners and Dyers, 1518-24 East 12th Street, Oakland, Calif.

(R. S. 4405, as amended, and 4462, as amended, 46 U. S. C. 375, 416. Interpret or apply R. S. 4417a, 4426, 4481, 4482, 4488, 4491, 4492, as amended, sec. 11, 35 Stat. 428, secs. 1, 2, 49 Stat. 1544, secs. 6, 17, 54 Stat. 164, 166, and sec. 3, 54 Stat. 346, as amended, sec. 3 (c), 68 Stat. 676; 46 U. S. C. 391a, 404, 474, 475, 481, 489, 490, 396, 367, 526e, 526p, 1333, 50 U. S. C. 198; E. O. 10402, 17 F. R. 9917, 3 CFR, 1952 Supp.; 46 CFR 160.006)

BUOYANT APPARATUS

Approval No. 160.010/21/0, 4.0′ x 6.0′ x 0.75′ buoyant apparatus, pine decking with copper tanks, 20-person capacity, general arrangement dwg. No. G-485, dated June 1955, manufactured by C. C. Galbraith & Son, Inc., 99 Park Place, New York 7, N. Y.

(R. S. 4405, as amended, and 4462, as amended, 46 U. S. C. 375, 416. Interpret or apply R. S. 4417a, as amended, 4426, as amended, 4488, as amended, 4491, as amended, secs. 1 and 2, 49 Stat. 1544, secs. 6 and 17, 54 Stat. 164, 166, as amended, sec. 3, 54 Stat. 346, as amended, and sec. 3 (c), 68 Stat. 676; 46 U. S. C. 391a, 404, 481, 489, 367, 526e, 526p, 1333, 50 U. S. C. 198; E. O. 10402, 17 F. R. 9917, 3 CFR, 1952 Supp.; 46 CFR 160.010)

GAS MASKS, SELF-CONTAINED BREATHING APPARATUS, AND SUPPLIED-AIR RESPIRATORS

Approval No. 160.011/1/1, MSA one-man combination fresh air hose mask, with all-vision facepiece assembly or with all-vision cleartone speaking diaphragm facepiece assembly which may be used in conjunction with the MSA Maskfone, Bureau of Mines Approval No. BM-1905A, MSA assembly dwg. No. A-1129-1 dated April 5, 1940, Rev. No. 4 dated August 29, 1950, manufactured by Mine Safety Appliances Co., 201 North Braddock Avenue, Pittsburgh 8, Pa. (Extension of the approval published in FEDERAL REGISTER November 11, 1950, effective November 11, 1955.)

Approval No. 160.011/2/1, MSA two-man combination fresh air hose mask, with all-vision facepiece assembly or with all-vision cleartone speaking diaphragm facepiece assembly which may be used in conjunction with the MSA Maskfone, Bureau of Mines Approval No. BM-1905A, MSA assembly dwg. No. A-1129-1 dated April 5, 1940, Rev. No. 4 dated August 29, 1950, manufactured by Mine Safety Appliances Co., 201 North Braddock Avenue, Pittsburgh 8, Pa. (Extension of the approval published in FEDERAL REGISTER November 11, 1950, effective November 11, 1955.)

Approval No. 160.011/12/1, MSA ammonia mask, with all-vision facepiece assembly or with all-vision cleartone speaking diaphragm facepiece assembly which may be used in conjunction with the MSA Maskfone, Bureau of Mines Approval No. BM-1406, MSA assembly dwg. No. A-1128-1 dated November 20, 1939, Rev. No. 10 dated August 29, 1950, manufactured by Mine Safety Appliances Co., 201 North Braddock Avenue, Pittsburgh 8, Pa. (Extension of the approval published in FEDERAL REGISTER November 11, 1950, effective November 11, 1955.)

Approval No. 160.011/15/1, MSA Model "S" all-service gas mask, with all-vision facepiece assembly or with all-vision cleartone speaking diaphragm facepiece assembly which may be used in conjunction with the MSA Maskfone, Bureau of Mines Approval No. BM-1434, MSA assembly dwg. No. A-1128-1 dated November 20, 1939, Rev. 10 dated August 29, 1950, manufactured by Mine Safety Appliances Co., 201 North Braddock Avenue, Pittsburgh 8, Pa. (Extension of the approval published in FEDERAL REGISTER November 11, 1950, effective November 11, 1955.)

Approval No. 160.011/18/1, MSA standard all-service gas mask, with all-vision facepiece assembly or with all-vision cleartone speaking diaphragm facepiece assembly which may be used in conjunction with the MSA Maskfone, Bureau of Mines Approval No. BM-1405, MSA assembly dwg. No. A-1128-1 dated November 20, 1939, Rev. No. 10 dated August 29, 1950, manufactured by Mine Safety Appliances Co., 201 North Braddock Avenue, Pittsburgh 8, Pa. (Extension of the approval published in FEDERAL REGISTER November 11, 1950, effective November 11, 1955.)

(R. S. 4405, as amended, and 4462, as amended, 46 U. S. C. 375, 416. Interpret or apply R. S. 4417a, as amended, 4426, as amended, 4491, as amended, secs. 1 and 2, 49 Stat. 1544, as amended, sec. 3, 54 Stat. 346, sec. 2, 54 Stat. 1028, as amended, and sec. 3 (c), 68 Stat. 676; 46 U. S. C. 391a, 404, 489, 367, 1333, 463a, 50 U. S. C. 198; E. O. 10402, 17 F. R. 9917, 3 CFR, 1952 Supp.; 46 CFR 160.011)

LIFE FLOATS

Approval No. 160.027/36/0, 7.67′ x 4.17′ (12″ dia. body section) rectangular hollow aluminum life float, 15-person capacity, general arrangement dwg. No. 80031, dated July 6, 1955, revised August 25, 1955, manufactured by Welin Davit and Boat Division of Continental Copper & Steel Industries, Inc., Perth Amboy, N. J.

(R. S. 4405, as amended, and 4462, as amended, 46 U. S. C. 375, 416. Interpret or apply R. S. 4417a, as amended, 4426, as amended, 4481, as amended, 4488, as amended, 4491, as amended, secs. 1 and 2, 49 Stat. 1544, as amended, sec. 3, 54 Stat. 346, as amended, and sec. 3 (c), 68 Stat. 676; 46 U. S. C. 391a, 404, 474, 481, 489, 367, 1333, 50 U. S. C. 198; E. O. 10402, 17 F. R. 9917, 3 CFR, 1952 Supp.; 46 CFR 160.027)

SIGNAL PISTOLS FOR PARACHUTE RED FLARE DISTRESS SIGNALS

Approval No. 160.028/6/1, signal pistol, dwg. No. SP-150 dated March 5, 1950, manufactured by Signal Pyrotechnic Co., 4041 Whiteside Steet, Los Angeles 63, Calif. (Extension of the approval published in FEDERAL REGISTER November 11, 1950, effective November 11, 1955.)

(R. S. 4405, as amended, and 4462, as amended, 46 U. S. C. 375, 416. Interpret or apply R. S. 4417a, as amended, 4426, as amended, 4488, as amended, 4491, as amended, secs. 1 and 2, 49 Stat. 1544, as amended, sec. 3, 54 Stat. 346, as amended, and sec. 3 (c), 68 Stat. 676; 46 U. S. C. 391a, 404, 481, 489, 367, 1333, 50 U. S. C. 198; E. O. 10402, 17 F. R. 9917, 3 CFR, 1952 Supp.; 46 CFR 160.028)

DAVITS, LIFEBOAT

Approval No. 160.032/68/1, mechanical davit, straight boom sheath screw, Type B-61 (formerly Type C), approved for maximum working load of 12,200 pounds per set (6,100 pounds per arm), using not less than two part falls, identified by arrangement dwg. No. 2549 dated March 13, 1943, and revised September 1, 1955, manufactured by Welin Davit and Boat Division of Continental Copper & Steel Industries, Inc., Perth Amboy, N. J. (Reinstates and supersedes Approval No. 160.032/68/0 terminated in FEDERAL REGISTER October 1, 1952.)

(R. S. 4405, as amended, and 4462, as amended, 46 U. S. C. 375, 416. Interpret or apply R. S. 4417a, as amended, 4426, as amended, 4481, as amended, 4488, as amended, 4491, as amended, secs. 1 and 2, 49 Stat. 1544, as amended, sec. 3, 54 Stat. 346, as amended, and sec. 3 (c), 68 Stat. 676; 46 U. S. C. 391a, 404, 474, 481, 489, 367, 1333, 50 U. S. C. 198; E. O. 10402, 17 F. R. 9917, 3 CFR, 1952 Cum. Supp.; 46 CFR 160.032)

LIFEBOATS

Approval No. 160.035/335/0, 28.0′ x 9.79′ x 4.13′ steel, motor-propelled lifeboat without radio cabin (Class B), 63-person capacity, identified by construction and arrangement dwg. No. 28-2B dated May 31, 1955, and revised July 14, 1955, manufactured by Marine Safety Equipment Corp., Point Pleasant, N. J.

(R. S. 4405, as amended, and 4462, as amended, 46 U. S. C. 375, 416. Interpret or apply R. S. 4417a, as amended, 4426, as amended, 4481, as amended, 4488, as amended, 4491, as amended, 4492, as amended, sec. 11, 35 Stat. 428, as amended, secs. 1 and 2, 49 Stat. 1544, as amended, sec. 3, 54 Stat. 346, as amended, and sec. 3 (c), 68 Stat. 676; 46 U. S. C. 391a, 404, 474, 481, 489, 490, 396, 367, 1333, 50 U. S. C. 198; E. O. 10402, 17 F. R. 9917, 3 CFR, 1952 Supp.; 46 CFR 160.035)

BUOYANT VESTS, KAPOK OR FIBROUS GLASS, ADULT AND CHILD MODELS AK, CKM, CKS, AF, CFM, AND CFS

Note: Approved for use on motorboats of Classes A, 1, or 2 not carrying passengers for hire.

Approval No. 160.047/43/0, Model AK, adult kapok buoyant vest, U. S. C. G. Specification Subpart 160.047, manufactured by Billy Boy Products, Inc., Quincy, Mich.

Approval No. 160.047/44/0, Model CKM, child kapok buoyant vest, U. S. C. G. Specification Subpart 160.047, manufactured by Billy Boy Products, Inc., Quincy, Mich.

Approval No. 160.047/45/0, Model CKS, child kapok buoyant vest, U. S. C. G. Specification Subpart 160.047, manufactured by Billy Boy Products, Inc., Quincy, Mich.

Approval No. 160.047/46/0, Model CKM, child kapok buoyant vest, U. S. C. G. Specification Subpart 160.047, manufactured by The Holiday Line, Inc., 54 Greene Street, New York 13, N. Y.

Approval No. 160.047/47/0, Model CKS, child kapok buoyant vest, U. S. C. G. Specification Subpart 160.047, manufactured by The Holiday Line, Inc., 54 Greene Street, New York 13, N. Y.

Approval No. 160.047/51/0, Model AK, adult kapok buoyant vest, U. S. C. G. Specification Subpart 160.047, manufactured by The American Pad & Textile Co., Greenfield, Ohio, for The Firestone Tire & Rubber Co., Akron 17, Ohio.

Approval No. 160.047/52/0, Model AK, adult kapok buoyant vest, U. S. C. G. Specification Subpart 160.047, manufactured by The Safegard Corp., Box 66, Station B, Cincinnati 22, Ohio, for Sears, Roebuck and Co., 925 South Homan Avenue, Chicago 7, Ill.

Approval No. 160.047/53/0, Model CKM, child kapok buoyant vest, U. S. C. G. Specification Subpart 160.047, manufactured by The Safegard Corp., Box 66, Station B, Cincinnati 22, Ohio, for Sears, Roebuck and Co., 925 South Homan Avenue, Chicago 7, Ill.

Approval No. 160.047/54/0, Model CKS, child kapok buoyant vest, U. S. C. G. Specification Subpart 160.047, manufactured by The Safegard Corp., Box 66, Station B, Cincinnati 22, Ohio, for Sears, Roebuck and Co., 925 South Homan Avenue, Chicago 7, Ill.

Approval No. 160.047/55/0, Model CKS, child kapok buoyant vest, U. S. C. G. Specification Subpart 160.047, manufactured by Atlas Products, 2459 University Avenue, St. Paul 14, Minn.

Approval No. 160.047/56/0, Model AK, adult kapok buoyant vest, U. S. C. G. Specification Subpart 160.047, manufactured by Noble Products Co., Box 327, Caldwell, Ohio.

Approval No. 160.047/57/0, Model CKM, child kapok buoyant vest, U. S. C. G. Specification Subpart 160.047, manufactured by Noble Products Co., Box 327, Caldwell, Ohio.

Approval No. 160.047/58/0, Model CKS, child kapok buoyant vest, U. S. C. G. Specification Subpart 160.047, manufactured by Noble Products Co., Box 327, Caldwell, Ohio.

Approval No. 160.047/59/0, Model AK, adult kapok buoyant vest, U. S. C. G. Specification Subpart 160.047, manufactured by Atlantic-Pacific Manufacturing Corp., 124 Atlantic Avenue, Brooklyn 1, N. Y., for Montgomery Ward & Co., Inc., 619 West Chicago Avenue, Chicago 7, Ill.

Approval No. 160.047/60/0, Model CKM, child kapok buoyant vest, U. S. C. G. Specification Subpart 160.047, manufactured by Atlantic-Pacific Manufacturing Corp., 124 Atlantic Avenue, Brooklyn 1, N. Y., for Montgomery Ward & Co., Inc., 619 West Chicago Avenue, Chicago 7, Ill.

Approval No. 160.047/61/0, Model CKS, child kapok buoyant vest, U. S. C. G. Specification Subpart 160.047, manufactured by Atlantic-Pacific Manufacturing Corp., 124 Atlantic Avenue, Brooklyn 1, N. Y., for Montgomery Ward & Co., Inc, 619 West Chicago Avenue, Chicago 7, Ill.

Approval No. 160.047/62/0, Model AK, adult kapok buoyant vest, U. S. C. G. Specification Subpart 160.047, manufactured by International Cushion Co., 1110 Northeast Eighth Avenue, Fort Lauderdale, Fla.

Approval No. 160.047/63/0, Model CKM, child kapok buoyant vest, U. S. C. G. Specification Subpart 160.047, manufactured by International Cushion Co., 1110 Northeast Eighth Avenue, Fort Lauderdale, Fla.

Approval No. 160.047/64/0, Model CKS, child kapok buoyant vest, U. S C. G. Specification Subpart 160.047, manufactured by International Cushion Co., 1110 Northeast Eighth Avenue, Fort Lauderdale, Fla.

Approval No. 160.047/65/0, Model CKM, child kapok buoyant vest, U. S. C. G. Specification Subpart 160.047, manufactured by Atlas Products, 2459 University Avenue, St. Paul 14, Minn.

Approval No. 160.047/66/0, Model AK, adult kapok buoyant vest, U. S. C. G. Specification Subpart 160.047, manufactured by Atlas Products, 2459 University Avenue, St. Paul 14, Minn.

Approval No. 160.047/67/0, Model CKS, child kapok buoyant vest, U. S. C. G. Specification Subpart 160.047, manufactured by The American Pad & Textile Co., Greenfield, Ohio, for Gamble-Skogmo, Inc., 15 North Eighth Street, Minneapolis 3, Minn.

Approval No. 160.047/68/0, Model CKM, child kapok buoyant vest, U. S. C. G. Specification Subpart 160.047, manufactured by The American Pad & Textile Co., Greenfield, Ohio, for Gamble-Skogmo, Inc., 15 North Eighth Street, Minneapolis 3, Minn.

Approval No. 160.047/69/0, Model AK, adult kapok buoyant vest, U. S. C. G. Specification Subpart 160.047, manufactured by The American Pad & Textile Co., Greenfield, Ohio, for Gamble-Skogmo, Inc., 15 North Eighth Street, Minneapolis 3, Minn.

(R. S. 4405, as amended, 4462, as amended; 46 U. S. C. 375, 416. Interpret or apply secs. 6, 17, 54 Stat. 164, 166, as amended; 46 U. S. C. 526e, 526p; 46 CFR 160.047)

BUOYANT CUSHIONS, KAPOK OR FIBROUS GLASS

NOTE: Approved for use on motorboats of Classes A, 1, or 2 not carrying passengers for hire.

Approval No. 160.048/26/0, group approval for rectangular and trapezoidal kapok buoyant cushions, U. S. C. G. Specification Subpart 160.048, sizes and weights of kapok filling to be as per Table 160.048-4 (c) (1) (i), manufactured by Red Head Brand Co., 4311 Belmont Avenue, Chicago 41, Ill.

Approval No. 160.048/28/0, group approval for rectangular or trapezoidal kapok buoyant cushions, U. S. C. G. Specification Subpart 160.048, sizes and weights of kapok filling to be as per Table 160.048-4 (c) (1) (i), manufactured by The Holiday Line, Inc., 54 Greene Street, New York 13, N. Y.

Approval No. 160.048/32/0, group approval for rectangular and trapezoidal kapok buoyant cushions, U. S. C. G. Specification Subpart 160.048, sizes and weights of kapok filling to be as per Table 160.048-4 (c) (1) (i), manufactured by Elvin Salow Co., 31-33 South Street, Boston 11, Mass.

Approval No. 160.048/33/0, group approval for rectangular or trapezoidal kapok buoyant cushions, U. S. C. G. Specification Subpart 160.048, sizes and weights of kapok to be as per Table 160.048-4 (c) (1) (i), manufactured by

Noble Products Company, Box 327, Caldwell, Ohio.

Approval No. 160.048/34/0, group approval for rectangular and trapezoidal kapok buoyant cushions, U. S. C. G. Specification Subpart 160.048, sizes and weights of kapok filling to be as per Table 160.048–4 (c) (1) (i), manufactured by The American Pad & Textile Co., Greenfield, Ohio, for The Firestone Tire & Rubber Co., Akron 17, Ohio.

Approval No. 160.048/35/0, group approval for rectangular and trapezoidal kapok buoyant cushions, U. S. C. G. Specification Subpart 160.048, sizes and weights of kapok filling to be as per Table 160.048–4 (c) (1) (i), manufactured by International Cushion Co., 1110 Northeast Eighth Avenue, Fort Lauderdale, Fla.

Approval No. 160.048/36/0, group approval for rectangular and trapezoidal kapok buoyant cushions, U. S. C. G. Specification Subpart 160.048, sizes and weights of kapok to be as per Table 160.048–4 (c) (1) (i), manufactured by The Safeguard Corp., Box 66, Station B, Cincinnati 22, Ohio, for Sears, Roebuck and Co., 925 South Homan Avenue, Chicago 7, Ill.

Approval No. 160.048/37/0, group approval for rectangular and trapezoidal kapok buoyant cushions, U. S. C. G. Specification Subpart 160.048, sizes and weights of kapok filling to be as per Table 160.048–4 (c) (1) (i), manufactured by The American Pad & Textile Co., Greenfield, Ohio, for Montgomery Ward & Co., 619 West Chicago Avenue, Chicago 7, Ill.

Approval No. 160.048/38/0, special approval for 14″ x 19″ x 2″ rectangular ribbed-type kapok buoyant cushion, 24 oz. kapok, American Pad & Textile Co., dwg. Nos. A–409, dated Sept. 28, 1955, and B–245, dated Feb. 15, 1955, manufactured by The American Pad & Textile Co., Greenfield, Ohio, for Montgomery Ward & Co., 619 West Chicago Avenue, Chicago 7, Ill.

Approval No. 160.048/39/0, group approval for rectangular and trapezoidal kapok buoyant cushions, U. S. C. G. Specification Subpart 160.048, sizes and weights of kapok filling to be as per Table 160.048–4 (c) (1) (i), manufactured by Atlantic-Pacific Manufacturing Corp., 124 Atlantic Avenue, Brooklyn 1, N. Y., for Montgomery Ward & Co., Inc., 619 West Chicago Avenue, Chicago 7, Ill.

Approval No. 160.048/40/0, group approval for rectangular or trapezoidal kapok buoyant cushions, U. S. C. G. Specification Subpart 160.048, sizes and weights of kapok filling to be as per Table 160.048–4 (c) (1) (i), manufactured by Fortier Upholstering Co., Manistee, Mich.

Approval No. 160.048/41/0, special approval for 13″ x 18″ x 2″ rectangular ribbed-type kapok buoyant cushion, 21 oz. kapok, dwg. No. 1, dated September 28, 1955, manufactured by Noble Products Co., Box 327, Caldwell, Ohio.

Approval No. 160.048/45/0, group approval for rectangular and trapezoidal kapok buoyant cushions, U. S. C. G. Specification Subpart 160.048, sizes and weights of kapok filling to be as per Table 160.048–4 (c) (1) (i), manufactured by A. L. Robertson, Inc., 113 South Gay Street, Baltimore 2, Md.

Approval No. 160.048/47/0, group approval for rectangular and trapezoidal kapok buoyant cushions, U. S. C. G. Specification Subpart 160.048, sizes and weights of kapok filling to be as per Table 160.048–4 (c) (1) (i), manufactured by The American Pad & Textile Co., Greenfield, Ohio, for Gamble-Skogmo, Inc., 15 North Eighth Street, Minneapolis 3, Minn.

Approval No. 160.048/48/0, special approval for 14″ x 17″ x 2″ rectangular ribbed-type kapok buoyant cushion, 21 oz. kapok, American Pad & Textile Co. dwg. Nos. A–766, dated October 24, 1955, and B–245, dated February 15, 1955, manufactured by The American Pad & Textile Co., Greenfield, Ohio, for Gamble-Skogmo, Inc., 15 North Eighth Street, Minneapolis 3, Minn.

Approval No. 160.048/49/0, group approval for rectangular and trapezoidal kapok buoyant cushions, U. S. C. G. Specification Subpart 160.048, sizes and weights of kapok filling to be as per Table 160.048–4 (c) (1) (i), manufactured by Style-Crafters, Inc., Box 3277, Station A, Greenville, S. C., for Montgomery Ward & Co., Inc., 619 West Chicago Avenue, Chicago 7, Ill.

(R. S. 4405, as amended, 4462, as amended; 46 U. S. C. 375, 416. Interpret or apply secs. 6, 17, 54 Stat. 164, 166, as amended; 46 U. S. C. 526e, 526p; 46 CFR 160.048)

BUOYANT CUSHIONS, UNICELLULAR PLASTIC FOAM

Note: Approved for use on motorboats of Classes A, 1, or 2 not carrying passengers for hire.

Approval No. 160.049/4/0, group approval for rectangular and trapezoidal unicellular plastic foam buoyant cushions, U. S. C. G. Specification Subpart 160.049, sizes to be as per Table 160.049–4 (c) (1), manufactured by Iowa Fibre Products, Inc., 316 Court Avenue, Des Moines 9, Iowa.

Approval No. 160.049/8/0, group approval for rectangular and trapezoidal unicellular plastic foam buoyant cushions, U S C. G. Specification Subpart 160.049, sizes to be as per Table 160.049–4 (c) (1), manufactured by The Safegard Corp., Box 66, Station B, Cincinnati 22, Ohio, for Sears, Roebuck and Co., 925 South Homan Avenue, Chicago 7, Ill.

Approval No. 160.049/9/0, group approval for rectangular and trapezoidal unicellular plastic foam buoyant cushions, U. S C. G. Specification Subpart 160.049, sizes to be as per Table 160.049–4 (c) (1), manufactured by Iowa Fibre Products Inc., 316 Court Avenue, Des Moines 9, Iowa, for Hawkeye Sporting Goods Co, P. O. Box 613, Des Moines, Iowa.

(R. S. 4405, as amended, 4462, as amended; 46 U. S. C. 375, 416. Interpret or apply secs. 6, 17, 54 Stat. 164, 166, as amended; 46 U. S. C. 526e, 526p; 46 CFR 160.049)

VALVES, SAFETY (POWER BOILERS)

Approval No. 162.001/137/1, Style HNA–MS–55 carbon steel body pop safety valve, flanged nozzle type, exposed spring fitted with spring cover, 1,500 p. s. i. primary service pressure rating, 650° F. maximum temperature, dwg. No. HV–25–MS issued June 3, 1950, and dwg. No. D–28167 issued March 11, 1947, approved for sizes 1½″, 2″, 2½″, 3″ and 4″, manufactured by Crosby Steam Gage & Valve Co., Wrentham, Mass. (Reinstates and supersedes Approval No. 162.001/137/0 terminated in the Federal Register September 29, 1955.)

Approval No. 162.001/138/1, Style HNA–MS–56 carbon steel body pop safety valve, flanged nozzle type, exposed spring fitted with spring cover, 1500 p. s. i. primary service pressure rating, 750° F. maximum temperature, dwg. No. HV–25–MS issued June 3, 1950, and dwg. No. D–28167 issued March 11, 1947, approved for sizes 1½″, 2″, 2½″, 3″, and 4″, manufactured by Crosby Steam Gage & Valve Co., Wrentham, Mass. (Reinstates and supersedes Approval No. 162.001/138/0 terminated in the Federal Register September 29, 1955.)

Approval No. 162.001/139/1, Style HNA–MS–57 alloy steel body pop safety valve, flanged nozzle type, exposed spring fitted with spring cover, 1500 p. s. i. primary service pressure rating, 900° F. maximum temperature, dwg. No. HV–26–MS, issued June 5, 1950 and dwg. No. D–28167 issued March 11, 1947, approved for sizes 1½″, 2″, 2½″, 3″ and 4″, manufactured by Crosby Steam Gage & Valve Co., Wrentham, Mass. (Reinstates and supersedes Approval No. 162.001/139/0 terminated in the Federal Register September 29, 1955.)

Approval No. 162.001/140/1, Style HNA–MS–58 alloy steel body pop safety valve, flanged nozzle type, exposed spring fitted with spring cover, 1,500 p. s. i. primary service pressure rating, 1,000° F. maximum temperature, dwg. No. HV–26–MS, issued June 5, 1950, and dwg. No. D–28167 issued March 11, 1947, approved for sizes 1½″, 2″, 2½″, 3″ and 4″, manufactured by Crosby Steam Gage & Valve Co., Wrentham, Mass. (Reinstates and supersedes Approval No. 162.001/140/0 terminated in the Federal Register September 29, 1955.)

(R. S. 4405, as amended, and 4462, as amended, 46 U. S. C. 375, 416. Interpret or apply R. S. 4417a, as amended, 4418, as amended, 4426, as amended, 4433, as amended, 4491, as amended, secs. 1 and 2, 49 Stat. 1544, as amended, sec. 3, 54 Stat. 346, as amended, and sec. 3 (c), 68 Stat. 676; 46 U. S. C. 391a, 392, 404, 411, 489, 367, 1333, 50 U. S. C. 198; E. O. 10402, 17 F. R. 9917, 3 CFR, 1952 Supp.; 46 CFR 162.001)

BOILERS, HEATING

Approval No. 162.003/65/2, size #1920–8C, steel plate heating boiler, steam or hot water, assembly & detail dwg. No. H–187 Rev. C. dated January 3, 1955, max. design pressure 30 p. s. i. approval limited to bare boiler, manufactured by Way-Wolff Associates, Inc., 33 Fulton Street, New York 38, N. Y. (Supersedes Approval No. 162.003/65/1 published in Federal Register March 21, 1951.)

(R. S. 4405, 4417a, 4418, 4426, 4433, 4434, 4491, as amended, secs. 1 and 2, 49 Stat. 1544, sec. 3, 54 Stat. 346, as amended, and sec. 3 (c), 68 Stat. 676; 46 U. S. C. 367, 375, 391a, 392, 404, 411, 412, 489, 1333, 50 U. S. C. 198; 46 CFR Part 52)

FIRE EXTINGUISHERS, PORTABLE, HAND, VAPORIZING LIQUID TYPE

Approval No. 162.004/82/1, Kidde Model 2VG (Symbol GEN), 1-qt. carbon tetrachloride vaporizing liquid pump type hand portable fire extinguisher, assembly dwg. No. BT-185-XK, Rev. C dated December 8, 1952, name plate dwg. No. T-185-A15 dated May 6, 1955 (Coast Guard classification: Type B, Size I; and Type C, Size I), manufactured for Walter Kidde & Co., Inc., Belleville 9, N. J., by The National Fireguard Corp., 1685 Shermer Road, Northbrook, Ill. (Supersedes Approval No. 162.004/82/0 published in FEDERAL REGISTER May 12, 1954.)

Approval No. 162.004/83/1, Kidde Model 3VG (Symbol GEN), 1½-qt. carbon tetrachloride vaporizing liquid pump type hand portable fire extinguisher, assembly dwg. No. BT-195-XK, Rev. D dated December 8, 1952, name plate dwg. No. T-195-A15 dated May 6, 1955 (Coast Guard classification: Type B, Size I; and Type C, Size I), manufactured for Walter Kidde & Co., Inc., Belleville 9, N. J., by The National Fireguard Corp., 1685 Shermer Road, Northbrook, Ill. (Supersedes Approval No. 162.004/83/0 published in FEDERAL REGISTER May 12, 1954.)

(R. S. 4405, 4417a, 4426, 4479, 4491, 4492, as amended, 49 Stat. 1544, and 54 Stat. 165, 166, 346, 1028, as amended, and sec. 3 (c), 68 Stat. 676; 46 U. S. C. 367, 375, 391a, 404, 463a, 472, 489, 490, 526g, 526p, 1333, 50 U. S. C. 198; 46 CFR 25.30, 34.25-1, 76.50, 95.50)

VALVES, RELIEF, HOT WATER HEATING BOILERS

Approval No. 162.013/4/1, Type No. 175 relief valve for hot water heating boilers, relieving capacity of 175,000 B. t. u. per hour at maximum set pressure of 30 p. s. i. dwg. No. RA3-11 dated September 2, 1955, approved for ¾'' inlet size, manufactured by Bell & Gossett Co., 8200 North Austin Avenue, Morton Grove, Ill. (Supersedes Approval No. 162.013/4/0 published in FEDERAL REGISTER February 17, 1951.)

Approval No. 162.013/5/1, Type No. 250 relief valve for hot water heating boilers, relieving capacity 250,000 B. t. u. per hour at maximum set pressure of 30 p. s. i., dwg. No. RA3-12 dated September 2, 1955, approved for ¾'' inlet size, manufactured by Bell & Gossett Co., 8200 North Austin Avenue, Morton Grove, Ill. (Supersedes Approval No. 162.013/5/0 published in FEDERAL REGISTER February 17, 1951.)

Approval No. 162.013/17/1, Type No. 175-15 relief valve for hot water heating boilers, relieving capacity 150,000 B. t. u. per hour at a maximum set pressure of 15 p. s. i., dwg. No. RA3-11, dated September 2, 1955, approved for ¾'' inlet size, manufactured by Bell & Gossett Co., 8200 North Austin Avenue, Morton Grove, Ill. (Supersedes Approval No. 162.013/17/0 published in FEDERAL REGISTER March 18, 1953.)

Approval No. 162.013/18/1, Type No. 1050 relief valve for hot water heating boilers, relieving capacity, 1,050,000 B. t. u. per hour at maximum set pressure of 30 p. s. i., dwg. No. RA-20, Rev. 1, dated September 21, 1955, approved for 1¼'' inlet size, manufactured by Bell & Gossett Co., 8200 North Austin Avenue, Morton Grove, Ill. (Supersedes Approval No. 162.013/18/0 published in FEDERAL REGISTER March 18, 1953.)

Approval No. 162.013/21/0, Type No. 250-15 relief valve for hot water heating boilers, relieving capacity 200,000 B. t. u. per hour at a maximum set pressure of 15 p. s. i., dwg. No. RA3-12, dated September 2, 1955, approved for ¾'' inlet size, manufactured by Bell & Gossett Co., 8200 North Austin Avenue, Morton Grove, Ill.

Approval No. 162.013/22/0, Type No. 350-15 relief valve for hot water heating boilers, relieving capacity 220,000 B. t. u. per hour at a maximum set pressure of 15 p. s. i., dwg. No. RA2-19, dated September 2, 1955, approved for ¾'' inlet size, manufactured by Bell & Gossett Co., 8200 North Austin Avenue, Morton Grove, Ill.

Approval No. 162.013/23/0, Type No. 350 relief valve for hot water heating boilers, relieving capacity 350,000 B. t. u. per hour at a maximum set pressure of 30 p. s. i., dwg. No. RA2-19, dated September 2, 1955, approved for ¾'' inlet size, manufactured by Bell & Gossett Co., 8200 North Austin Avenue, Morton Grove, Ill.

Approval No. 162.013/24/0, Type No. 480-15 relief valve for hot water heating boilers, relieving capacity 300,000 B. t. u. per hour at a maximum set pressure of 15 p. s. i., dwg. No. RA-23, dated September 26, 1955, approved for ¾'' inlet size, manufactured by Bell & Gossett Co., 8200 North Austin Avenue, Morton Grove, Ill.

Approval No. 162.013/25/0, Type No. 480 relief valve for hot water heating boilers, relieving capacity 480,000 B. t. u. per hour at a maximum set pressure of 30 p. s. i., dwg. No. RA-23, dated September 26, 1955, approved for ¾'' inlet size, manufactured by Bell & Gossett Co., 8200 North Austin Avenue, Morton Grove, Ill.

Approval No. 162.013/26/0, Type No. 750-15 relief valve for hot water heating boilers, relieving capacity 500,000 B. t. u. per hour at a maximum set pressure of 15 p. s. i., dwg. No. RA-24, dated September 23, 1955, approved for 1'' inlet size, manufactured by Bell & Gossett Co., 8200 North Austin Avenue, Morton Grove, Ill.

Approval No. 162.013/27/0, Type No. 750 relief valve for hot water heating boilers, relieving capacity 750,000 B. t. u. per hour at a maximum set pressure of 30 p. s. i., dwg. No. RA-24, dated September 23, 1955, approved for 1'' inlet size, manufactured by Bell & Gossett Co., 8200 North Austin Avenue, Morton Grove, Ill.

Approval No. 162.013/28/0, Type No. 1050-15 relief valve for hot water heating boilers, relieving capacity 650,000 B. t. u. per hour at a maximum set pressure of 15 p. s. i., dwg. No. RA-20, Rev. 1, dated September 21, 1955, approved for 1¼'' inlet size, manufactured by Bell & Gossett Co., 8200 North Austin Avenue., Morton Grove, Ill.

Approval No. 162.013/29/0, Type No. N74 relief valve for hot water heating boilers, relieving capacity of 690,000 B. t. u. per hour at a maximum set pressure of 30 p. s. i., dwg. No. N74-N174 P. D., dated October 7, 1952, approved for ¾'' inlet size, manufactured by Watts Regulator Co., Lawrence, Mass.

Approval No. 162.013/30/0, Type No. N174 relief valve for hot water heating boilers, dwg. No. N74-N174 P. D., dated October 7, 1952, approved for the following sizes and relieving capacities:

Inlet size (inches):	*Relieving capacity (B. t. u. per hr. at 30 p. s. i.)*
¾	470,000
1	870,000
1¼	1,345,000
1½	2,020,000
2	3,815,000

manufactured by Watts Regulator Company, Lawrence, Mass.

(R. S. 4405, as amended, and 4462, as amended, 46 U. S. C. 375, 416. Interpret or apply R. S. 4417a, as amended, 4418, as amended, 4426, as amended, 4433, as amended, 4491, as amended, secs. 1 and 2, 49 Stat. 1544, as amended, sec. 3, 54 Stat. 346, as amended, and sec. 3 (c), 68 Stat. 676; 46 U. S. C. 391a, 392, 404, 411, 489, 367, 1333, 50 U. S. C. 198; E. O. 10402, 17 F. R. 9917, 3 CFR, 1952 Supp.; 46 CFR 162.013)

CHANGE IN ADDRESS OF MANUFACTURER

The address of The American Pad & Textile Co., Greenfield, Ohio, has been changed to The American Pad & Textile Co., Greenfield, Ohio; New Orleans, La., and Fairfield, Calif., for Approval Nos. 160.048/3/0, 160.048/4/0, 160.048/5/0, and 160.048/6/0 previously published in the FEDERAL REGISTER.

Dated: December 13, 1955.

[SEAL] A. C. RICHMOND,
Vice Admiral, U. S. Coast Guard, Commandant.

[F. R. Doc. 55-10159; Filed, Dec. 19, 1955; 8:48 a. m.]

CIVIL AERONAUTICS BOARD

[Docket No. 7518]

AIR AMBULANCE SERVICE; SASKATCHEWAN

NOTICE OF HEARING ON APPLICATION FOR RENEWAL OF FOREIGN AIR CARRIER PERMIT

In the matter of the application of Air Ambulance Service, Department of Public Health, Government of Saskatchewan, for renewal of the foreign air carrier permit issued pursuant to section 402 of the Civil Aeronautics Act, to perform operations of a casual, occasional or infrequent nature, in common carriage, into the United States.

Notice is hereby given that a hearing in the above-entitled proceeding is assigned to be held on December 27, 1955, at 11:00 a. m., e. s. t., in Room E-206, Temporary Building No. 5, Sixteenth Street and Constitution Avenue NW., Washington, D. C., before Examiner Joseph L. Fitzmaurice.

Dated at Washington, D. C., December 15, 1955.

[SEAL] FRANCIS W. BROWN,
Chief Examiner.

[F. R. Doc. 55-10185; Filed, Dec. 19, 1955; 8:52 a. m.]

[Docket No. 7517]

QUEEN CHARLOTTE AIRLINES LTD.

NOTICE OF HEARING ON APPLICATION FOR EXTENSION OF FOREIGN AIR CARRIER PERMIT

In the matter of the application of Queen Charlotte Airlines Ltd. for an extension of foreign air carrier permit dated November 20, 1952 issued pursuant to section 402 of the Civil Aeronautics Act to perform operations of a regular nature between the terminal point Ketchikan, Alaska and the terminal Prince Rupert, British Columbia.

Notice is hereby given that a hearing in the above-entitled proceeding is assigned to be held on December 27, 1955, at 10:00 a. m., e. s. t., in Room E-206, Temporary Building No. 5, Sixteenth Street and Constitution Avenue NW., Washington, D. C., before Examiner Joseph L. Fitzmaurice.

Dated at Washington, D. C., December 15, 1955.

FRANCIS W. BROWN,
Chief Examiner.

[F. R. Doc. 55-10186; Filed, Dec. 19, 1955; 8:52 a. m.]

FEDERAL COMMUNICATIONS COMMISSION

[Docket No. 11029; FCC 55M-1031]

VOICE OF LAKE TAHOE

ORDER SCHEDULING HEARING

In re application of Charles E. Halstead, tr/as Voice of Lake Tahoe, Zephyr Cove, Nevada, Docket No. 11029, File No. BP-9108; for construction permit.

The Hearing Examiner having under consideration a Motion to Fix Date for Hearing filed November 29, 1955, on behalf of the Chief, Broadcast Bureau, Federal Communications Commission; and

It appearing that the hearing in this proceeding was continued by Hearing Examiner's order of September 21, 1954, until such time as may be established by a subsequent order pending Commission action on (1) another application that might be designated for hearing in consolidation with the above application, and (2) a Petition to the Full Commission for Reconsideration and Grant of the instant application; and

It further appearing that the Commission's records indicate that the application referred to in (1) above was dismissed at the applicant's request on August 9, 1955, and that the petition for reconsideration and grant was denied by Commission's order released November 17, 1955; and

It further appearing that no objection to the instant motion has been filed and that a grant thereof will conduce to the orderly dispatch of the Commission's business; now therefore

It is ordered, This 13th day of December 1955, that the Motion to Fix Date for Hearing be and it is hereby granted, and that the hearing in this proceeding shall be commenced at 10:00 a. m. on Thursday, January 26, 1956, at the offices of the Commission in Washington, D. C.; and

It is further ordered, That the Secretary send a copy of this order by Registered Mail—Return Receipt Requested to the applicant named at P. O. Box 19, Zephyr Cove, Nevada.

FEDERAL COMMUNICATIONS
COMMISSION,
[SEAL] MARY JANE MORRIS,
Secretary.

[F. R. Doc. 55-10163; Filed, Dec. 19, 1955; 8:49 a. m.]

[Docket No. 11571; FCC 55M-1034]

JOHNSONVILLE BROADCASTING CO.

ORDER SCHEDULING HEARING

In re application of Dr. Alexander Leech and William E. Leech, d/b as Johnsonville Broadcasting Company, New Johnsonville, Tennessee, Docket No. 11571, File No. BP-9810; for construction permit.

It is ordered, This 13th day of December 1955, that Annie Neal Huntting will preside at the hearing in the above-entitled proceeding which is hereby scheduled to commence on February 20, 1956, in Washington, D. C.

Released: December 14, 1955.

FEDERAL COMMUNICATIONS
COMMISSION,
[SEAL] MARY JANE MORRIS,
Secretary.

[F. R. Doc. 55-10164; Filed, Dec. 19, 1955; 8:49 a. m.]

[Docket Nos. 11493, 11494; FCC 55M-1030]

RADIO BROADCASTING SERVICE AND DANA W. ADAMS

FIRST STATEMENT CONCERNING PRE-HEARING CONFERENCES AND ORDER CONTINUING HEARING

In re applications of Louis Alford, Phillip D. Brady and Albert Mack Smith, d/b as Radio Broadcasting Service, Tyler, Texas, Docket No. 11493, File No. BP-9761; Dana W. Adams, Tyler, Texas, Docket No. 11494, File No. BP-9841; for construction permits.

The first pre-hearing conference was held herein on December 12, 1955. Both applicants and the Commission's Broadcast Bureau were represented by counsel. Neither of the respondents, Alto, Inc. (KAND), and Southwestair (KSWA), filed appearances pursuant to section 1.387 of the Commission's rules or appeared at the pre-hearing conference, as directed by the Hearing Examiner's order of November 15, 1955. On motion of counsel for Radio Broadcasting Service, the Hearing Examiner held each of the respondents to be in default. It was agreed, however, that the Hearing Examiner might reconsider this ruling provided a petition for reconsideration was filed by either respondent within 10 days after the date of this conference.

Agreements were reached among the parties and stated on the record, as reflected in the transcript which is incorporated herein by reference. Such agreements are found to be acceptable and approved by the Hearing Examiner. They include the following:

1. The direct cases, in written form, shall be prepared as follows:

(a) The testimony of each witness shall be prepared in narrative form and shall be submitted under the affidavit of the particular witness.

(b) All narrative statements (except engineering exhibits) shall be prepared in double-spaced form; each page and each line shall be numbered, and carbon copies shall not be acceptable.

(c) Parties shall be designated by abbreviated names, as follows: Radio, Adams, KAND, KSWA and Commission Counsel.

(d) Each party shall mark each of its exhibits with its name and a number. Narrative statements shall be numbered in series, beginning with one. An exhibit connected with a narrative statement shall be given the same number as the narrative statement, plus an identifying letter in series, such as "Radio No. 1-A." (Engineering exhibits may vary from this style.)

2. Where the direct case in written form contains testimony of witnesses whose direct testimony appropriately could have been taken by deposition, parties will not object to taking cross-examination of such witnesses through deposition procedures rather than requiring those witnesses to be brought to Washington.

3. With reference to program proposals in direct cases: unless a stipulation to the contrary is reached, applicants will submit, as a minimum, (a) complete program schedule of programs, including the classification of each program by type and source; (b) non-network program descriptions; (c) analyses of proposed typical week by type and source, together with information on spot announcements as required by FCC Form 301.

4. The direct written cases shall be exchanged on or before January 6, 1956.

5. On or before January 13, 1956, counsel for each party shall serve upon all other counsel, and file with the Commission in triplicate, a written statement containing (a) a list of all objections it desires to make to the receipt in evidence of any exhibits or specific portions thereof contained in the direct cases already exchanged, together with a brief statement of the reason for each objection; and (b) additional information it desires from other party or parties.

6. On or before January 18, 1956, counsel for all parties shall meet in informal conference, without the Hearing Examiner, for the purpose of discussing such objections and requests for information and reaching agreements thereon insofar as possible. All agreements reached shall be reduced to writing, signed by the parties, and filed with the Commission in triplicate on or before January 20, 1956, together with a list of the objections on which agreement was not reached and information refused to be furnished.

7. On or before January 20, 1956, each party shall serve upon all other parties, and file with the Commission in triplicate, a notice stating which witnesses it

desires to be produced for cross-examination (a) in Washington, or (b) through deposition procedures.

8. All parties shall attempt to reach a stipulation with reference to engineering facts.

9. On January 25, 1956, at 10:00 a. m., a further pre-hearing conference shall be held for the purposes stated in section 1.841 (c).

10. Hearing is continued from January 12, 1956, to 10:00 a. m., January 31, 1956.

It is ordered, This 12th day of December 1955, that the foregoing agreements and requirements shall govern the course of the proceeding to the extent indicated, unless modified by the Hearing Examiner for cause or by the Commission upon review of the Hearing Examiner's ruling; and the hearing herein, now scheduled for January 12, 1956, is continued until January 31, 1956, at 10:00 a. m.; and the second pre-hearing conference is scheduled for January 25, 1956, at 10:00 a. m.

FEDERAL COMMUNICATIONS
COMMISSION,
[SEAL] MARY JANE MORRIS,
Secretary.

[F. R. Doc. 55-10165; Filed, Dec. 19, 1955; 8:49 a. m.]

[Docket No. 11573]

JESSE ZORN

ORDER TO SHOW CAUSE WHY RADIOTELEPHONE STATION LICENSE SHOULD NOT BE REVOKED

There being under consideration the matter of certain alleged violations of the Commission's rules in connection with the operation of station WE-8900 licensed to Jesse Zorn, Aransas Pass, Texas, and located aboard the vessel "Golden West";

It appearing that notices of the violations of the Commission's rules in the operation of said station were given the licensee as follows:

(a) Notice dated April 4, 1955, specifying, among other things, violation of section 8.108 of the Commission's rules on April 1, 1955, by transmitting harmonic emissions so as to cause undue interference;

(b) Notice dated May 9, 1955, sent by Registered Mail, Return Receipt Requested, which was received by the licensee on May 10, 1955, calling attention to the above-noted violation and failure to reply thereto in violation of section 8.601 (a) of the Commission's rules. This notice also requested a reply within 10 days of receipt;

It further appearing that as of this date the licensee has not answered either of the above-mentioned official violation notices;

It is ordered, This 14th day of December 1955 pursuant to the provisions of section 312 (c) of the Communications Act of 1934, as amended, that the said Jesse Zorn, Aransas Pass, Texas, show cause why the aforementioned license should not be revoked and appear and give evidence in respect thereto at a hearing[1] to be held before this Commission, at Washington, D. C., on the 21st day of February, 1956;

It is further ordered, That the Secretary send a copy of this Order to the licensee by Registered Mail—Return Receipt Requested.

Released: December 15, 1955.

FEDERAL COMMUNICATIONS
COMMISSION,
[SEAL] MARY JANE MORRIS,
Secretary.

[F. R. Doc. 55-10166; Filed, Dec. 19, 1955; 8:49 a. m.]

[Docket No. 11574]

WARNER AND TAMBLE RADIO SERVICE, INC.

ORDER TO SHOW CAUSE WHY LICENSE FOR RADIOTELEPHONE STATION SHOULD NOT BE REVOKED

There being under consideration the matter of certain alleged violations of the Commission's rules in connection with the operation of station WA-7204, licensed to Warner and Tamble Radio Service, Inc., P. O. Box 166, Memphis 1, Tennessee and located aboard the vessel "Lin Smith";

It appearing that notices of the violations of the Commission's rules in the operation of said station were given the licensee as follows:

(a) Notice dated June 6, 1955, specifying among other things, that on March 25, 1955, said licensee had violated section 8.364 of the Commission's rules by failure to announce the assigned call letters at the beginning and conclusion of its communications;

(b) Notice dated July 22, 1955, sent by Registered Mail, Return Receipt Requested, which was received by the licensee on July 26, 1955, calling attention to the above-noted violation and also the further violation of section 8.601 (a) of Commission's rules for failure to respond thereto. This notice also requested a reply within 10 days of receipt;

It further appearing that as of this date the licensee has not answered either of the above-mentioned official violation notices;

It is ordered, This 14th day of December 1955 pursuant to the provisions of section 312 (c) of the Communications Act of 1934, as amended, that the said Warner and Tamble Radio Service, Inc., P. O. Box 166, Memphis 1, Tennessee, show cause why the aforementioned license should not be revoked and appear and give evidence in respect thereto at a hearing[1] to be held before this Commission at Washington, D. C., on the 13th day of February 1956;

It is further ordered, That the Secretary send a copy of this Order to the licensee by Registered Mail—Return Receipt Requested.

Released: December 15, 1955.

FEDERAL COMMUNICATIONS
COMMISSION,
[SEAL] MARY JANE MORRIS,
Secretary.

[F. R. Doc. 55-10167; Filed, Dec. 19, 1955; 8:49 a. m.]

[Docket No. 11575]

MISSISSIPPI VALLEY BARGE LINE CO.

ORDER TO SHOW CAUSE WHY LICENSE FOR RADIOTELEPHONE STATION SHOULD NOT BE REVOKED

There being under consideration the matter of certain alleged violations of the Commission's rules in connection with the operation of station WA-7349 licensed to the Mississippi Valley Barge Line Company, 1017 Olive Street, St. Louis, Missouri, and located aboard the vessel "Louisiana";

It appearing that notices of the violations of the Commission's rules in the operation of said station were given the licensee as follows:

(a) Notice dated May 18, 1955, specifying, among other things, that said licensee on April 24, 1955, failed to announce call letters at the beginning and upon conclusion of communications in violation of section 8.364 of the Commission's rules.

(b) Notice dated July 25, 1955, by Registered Mail, Return Receipt Requested, warning the licensee concerning the above violation and failure to respond thereto in violation of section 8.601 (a) of the Commission's rules. This notice was received by the licensee on July 27, 1955, and requested a response within 10 days of receipt;

It further appearing that as of this date the licensee has not answered either of the above-mentioned official violation notices;

It is ordered, This 14th day of December 1955 pursuant to section 312 (c) of the Communications Act of 1934, as amended, that the said Mississippi Valley Barge Line Company show cause why the aforesaid license should not be revoked and appear and give evidence in respect thereto at a hearing[1] to be held before this Commission at Washington, D. C., on the 15th day of February 1956;

It is further ordered, That the Secretary send a copy of this Order by Registered Mail, Return Receipt Requested, to the said Mississippi Valley Barge Line Company, 1017 Olive Street, St. Louis, Missouri.

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[1] Section 1.402 of the Commission's rules provides that in order to have the opportunity to appear before the Commission at the time and place specified in an order to show cause, a licensee shall within thirty (30) days from the date of the receipt of a show cause order submit a written statement informing the Commission whether said licensee will appear at the designated hearing and present evidence upon the matters specified, or whether the rights to such a hearing are waived. Waiver of the hearing may be accompanied by a statement setting forth the reasons why the licensee believes that an order of revocation should not be issued. A waiver unaccompanied by such a statement will be deemed to be an admission of the allegations specified in the order to show cause. Failure to respond to a show cause order within the above-mentioned thirty (30) day period, or, having informed the Commission in writing within the above-mentioned thirty (30) day period that the licensee will appear at the hearing and present evidence upon the matter specified and then failing to appear at the hearing, will be deemed to be a waiver of the right to a hearing and an admission of the allegations specified in the order to show cause.

Released: December 15, 1955.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] MARY JANE MORRIS,
Secretary.

[F. R. Doc. 55-10168; Filed, Dec. 19, 1955; 8:49 a. m.]

[Docket No. 11576]

DUNCAN CAMERON

ORDER TO SHOW CAUSE WHY LICENSE FOR RADIOTELEPHONE STATION SHOULD NOT BE REVOKED

There being under consideration the matter of certain alleged violations of the Commission's rules in connection with the operation of station WE-5783 licensed to Duncan Cameron and located aboard the vessel "Kimberly";

It appearing that notices of the violations of the Commission's rules in the operation of said station were given to the licensee as follows:

(a) Notice dated June 8, 1955, specifying, among other things, that on April 21 and 22, 1955, said licensee violated section 8.364 of the Commission's rules by failing to announce the assigned call letters at the beginning and at the end of the communication;

(b) Notice dated July 22, 1955, sent by Registered Mail, Return Receipt Requested, received by the licensee on July 29, 1955, calling attention to the above noted violations and also the further violation of section 8.601 (a) of the Commission's rules for failure to reply thereto. This notice also requested a response within 10 days of receipt;

It further appearing that as of this date the licensee has not answered either of the above-mentioned official violation notices;

It is ordered, This 14th day of December 1955 pursuant to the provisions of section 312 (c) of the Communications Act of 1934, as amended, that the said Duncan Cameron, P. O. Box 1906, Fort Myers, Florida, show cause why the aforementioned license should not be revoked and appear and give evidence in respect thereto at a hearing[1] to be held before this Commission at Washington, D. C., on the 21st day of February, 1956;

It is further ordered, That the Secretary send a copy of this Order to the licensee by Registered Mail—Return Receipt Requested.

Released: December 15, 1955.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] MARY JANE MORRIS,
Secretary.

[F. R. Doc. 55-10169; Filed, Dec. 19, 1955; 8:49 a. m.]

[Cuba Change List 6]

CUBAN RADIO STATIONS

NOTIFICATION OF NEW STATIONS, CHANGES, MODIFICATION AND DELETIONS OF EXISTING STATIONS

NOVEMBER 18, 1955.

Notification of new Cuban radio stations, and of changes, modification and deletions of existing stations, in accordance with part III, section F, of the North American Regional Broadcasting Agreement, Washington, D. C. 1950.

Call letters	Location	Power (kw)	Antenna	Schedule	Class	Probable date of change or commencement of operation
		630 kilocycles				
CMQ	Habana, Habana	50	DA-1	U	I-D	
		740 kilocycles				
CMAB	Pinar del Rio	5	ND	U	II	
		790 kilocycles				
CMCH	Habana, Habana	10	DA-1	U	III-E	
		910 kilocycles				
New	Matanzas	0.25	ND	U	IV	Synchronized with CMCF.
		970 kilocycles				
CMHZ	Santa Clara, Las Villas	1	ND	U	III	Provisional operation.
		1150 kilocycles				
CMCM	Habana, Habana (vide: 1460 kc) (delete).	0.25	ND	U	III	Mar. 26, 1955.
		1200 kilocycles				
CMDD	Bayamo, Oriente	0.25	ND	U	II	Dec. 10, 1954.
		1260 kilocycles				
CMDE	Bayamo, Oriente	0.25	ND	U	IV	
		1290 kilocycles				
CMDC	Holguin, Oriente (vide: 1360 kc)	1	ND	U	III	
		1360 kilocycles				
CMBG	Habana, Habana (change in call letters).	0.25	ND	U	IV	
CMDC	Holguin, Oriente (PO: 1290 kc 1 kw).	1D/5N	ND	U	III	
		1460 kilocycles				
CMZ	Habana (vide: 1560 kc) (delete)	0.5	ND	U	III	
		1490 kilocycles				
CMOX	Habana (change in call letters)	0.25	ND	U	IV	
		1560 kilocycles				
CMZ	Habana (PO: 0.5 kw 1460 kc)	5	ND	U	III	
		1580 kilocycles				
CMJS	Ciego de Avila, Camaguey (correction of error in call letters).	0.25	ND	U	II	

[SEAL] FEDERAL COMMUNICATIONS COMMISSION,
MARY JANE MORRIS,
Secretary.

[F. R. Doc. 55-10171; Filed, Dec. 19, 1955; 8:50 a. m.]

[Docket No. 11579]

SCHOONER CORP.

ORDER TO SHOW CAUSE WHY LICENSE FOR RADIOTELEPHONE STATION SHOULD NOT BE REVOKED

There being under consideration the matter of certain alleged violations of the Commission's rules in connection with the operation of station WC-4763, licensed to Schooner Corporation, 20 Fish Pier, Boston 10, Massachusetts, and located aboard the vessel "Ocean Clipper";

It appearing that notices of the violations of the Commission's rules were given the licensee as follows:

(a) Notice dated July 27, 1955, specifying among other things, that said licensee on July 12, 1955, had violated the following Commission's rules:

(1) Section 8.364 (a) by failing to identify the aforesaid station by the assigned call sign;

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[1] Section 1.402 of the Commission's rules provides that in order to have the opportunity to appear before the Commission at the time and place specified in an order to show cause, a licensee shall within thirty (30) days from the date of the receipt of a show cause order submit a written statement informing the Commission whether said licensee will appear at the designated hearing and present evidence upon the matters specified, or whether the rights to such a hearing are waived. Waiver of the hearing may be accompanied by a statement setting forth the reasons why the licensee believes that an order of revocation should not be issued. A waiver unaccompanied by such a statement will be deemed to be an admission of the allegations specified in the order to show cause. Failure to respond to a show cause order within the above-mentioned thirty (30) day period, or, having informed the Commission in writing within the above-mentioned thirty (30) day period that the licensee will appear at the hearing and present evidence upon the matter specified and then failing to appear at the hearing, will be deemed to be a waiver of the right to a hearing and an admission of the allegations specified in the order to show cause.

(2) Section 8.131 by operating with a frequency deviation greater than the tolerance allowed.

(b) Notice dated September 28, 1955, sent by Registered Mail, Return Receipt Requested, which was received by the licensee on September 29, 1955, calling attention to the above noted violations and the further violation of section 8.601 (a) for failure to reply thereto. The licensee was also requested to respond within ten days of receipt;

It further appearing that as of this date the licensee has not answered either of the above-mentioned official violation notices;

It is ordered, This 14th day of December 1955, pursuant to the provisions of section 312 (c) of the Communications Act of 1934, as amended, that the said Schooner Corporation, 20 Fish Pier, Boston 10, Massachusetts, show cause why the aforementioned license should not be revoked and appear and give evidence in respect thereto at a hearing[1] to be held before this Commission at Washington, D. C., on the 17th day of February, 1956;

It is further ordered, That the Secretary send a copy of this Order to the licensee by Registered Mail—Return Receipt Requested.

Released: December 15, 1955.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] MARY JANE MORRIS,
Secretary.

[F. R. Doc. 55-10170; Filed, Dec. 19, 1955; 8:50 a. m.]

[Cuba Change List 7]

CUBAN RADIO STATIONS

NOTIFICATION OF NEW STATIONS, CHANGES, MODIFICATION AND DELETIONS OF EXISTING STATIONS

NOVEMBER 25, 1955.

Notification of new Cuban radio stations, and of changes, modification and deletions of existing stations, in accordance with part III, section F, of the North American Regional Broadcasting Agreement, Washington, D. C., 1950.

Call letters	Location	Power (kw)	Antenna	Schedule	Class	Probable date of change or commencement of operation
		680 kilocycles				
CMHN	Cienfuegos, Las Villas	1D/5N	ND	U	II	
		1,280 kilocycles				
CMHA	Santa Clara, Las Villas	1	ND	U	III	Correction re power.

FEDERAL COMMUNICATIONS COMMISSION,
[SEAL] MARY JANE MORRIS,
Secretary.

[F. R. Doc. 55-10172; Filed, Dec. 19, 1955; 8:50 a. m.]

FEDERAL POWER COMMISSION

[Docket Nos. G-8854—8864 etc.]

C. R. RIDGWAY ET AL.

NOTICE OF SEVERANCE

DECEMBER 14, 1955.

In the matters of C. R. Ridgway and W. B. Ridgway, Docket Nos. G-8854—G-8864, incl.; Granite Oil Trust No. 2 of Oklahoma, Docket No. G-8915; A. J. Hodges Industries, Inc., Docket No. G-8975; States Oil Company, et al., Docket No. G-8992; Robert B. Prentice, et al., Docket No. G-9018; W. Earl Rowe, et al., Docket No. G-9026; Sunray Mid-Continent Oil Company, Docket No. G-9043; Flanders Gas & Oil Company, Docket No. G-9052; J. C. Vaughan, Jr., Docket No. G-9160; A. E. Coutant, Docket No. G-9167.

By notice issued November 30, 1955, the above-captioned proceedings were consolidated and set down for hearing in Washington, D. C., on December 20, 1955.

Each of the above applications for certificate of public convenience and necessity involves the sale of natural gas in interstate commerce to United Gas Pipe Line Company for resale. In addition, however, the proceeding in Docket No. G-9052 involves an application for a certificate authorizing the acquisition of natural-gas properties.

It appears appropriate, therefore, to sever Docket No. G-9052 from the above-captioned proceedings, and to that end:

The proceeding in Docket No. G-9052 be and it is hereby severed from the proceedings consolidated with Docket No. G-8854.

Also take notice that the public hearing concerning the matters involved in and the issues presented by the application for a certificate of public convenience and necessity in Docket No. G-9052 will be held at a date and time to be fixed by further notice.

[SEAL] LEON M. FUQUAY,
Secretary.

[F. R. Doc. 55-10181; Filed, Dec. 19, 1955; 8:52 a. m.]

[Docket No. G-1463]

SOUTHERN NATURAL GAS CO.

NOTICE OF ORDER REGARDING CERTIFICATE OF PUBLIC CONVENIENCE AND NECESSITY

DECEMBER 14, 1955.

Notice is hereby given that on November 29, 1955, the Federal Power Commission issued its order adopted November 23, 1955, in the above-entitled matter, modifying order issued November 21, 1950 (15 F. R. 8095), issuing a certificate of public convenience and necessity authorizing the construction and operation of facilities for the sale and delivery of natural gas to Mississippi Valley Gas Company, in lieu of the North Central Gas District and the Carthage Gas District.

[SEAL] LEON M. FUQUAY,
Secretary.

[F. R. Doc. 55-10182; Filed, Dec. 19, 1955; 8:52 a. m.]

[Docket No. G-9218]

NATURAL GAS CO. OF WESTERN CAROLINA

NOTICE OF DECLARATION OF EXEMPTION

DECEMBER 14, 1955.

Notice is hereby given that on November 29, 1955, the Federal Power Commission issued its declaration of exemption from the provisions of the Natural Gas Act adopted November 23, 1955, in the above-entitled matter.

[SEAL] LEON M. FUQUAY,
Secretary.

[F. R. Doc. 55-10183; Filed, Dec. 19, 1955; 8:52 a. m.]

[Docket No. G-6098]

SOUTHERN PRODUCTION CO., INC.

NOTICE OF APPLICATION AND DATE OF HEARING

DECEMBER 14, 1955.

Take notice that Southern Production Company, Inc. (Applicant), a Delaware corporation whose address is Fort Worth, Texas, filed on November 26, 1954, an application for a certificate of public convenience and necessity to continue making sales in interstate commerce of natural gas for resale, pursuant to section 7 of the Natural Gas Act, authorizing Applicant to render service as hereinafter described, subject to the jurisdiction of the Commission, all as more fully represented in the application which is on file with the Commission and open for public inspection.

Applicant produces natural gas from the Panhandle and Sprayberry Trend

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[1] Section 1.402 of the Commission's rules provides that in order to have the opportunity to appear before the Commission at the time and place specified in an order to show cause, a licensee shall within thirty (30) days from the date of the receipt of a show cause order submit a written statement informing the Commission whether said licensee will appear at the designated hearing and present evidence upon the matters specified, or whether the rights to such a hearing are waived. Waiver of the hearing may be accompanied by a statement setting forth the reasons why the licensee believes that an order of revocation should not be issued. A waiver unaccompanied by such a statement will be deemed to be an admission of the allegations specified in the order to show cause. Failure to respond to a show cause order within the above-mentioned thirty (30) day period, or, having informed the Commission in writing within the above-mentioned thirty (30) day period that the licensee will appear at the hearing and present evidence upon the matter specified and then failing to appear at the hearing, will be deemed to be a waiver of the right to a hearing and an admission of the allegations specified in the order to show cause.

Gas Fields located in Gray, Upton, Reagan, Midland and Glasscock Counties, Texas, which it sells in interstate commerce to the following buyers for resale: Phillips Petroleum Company who resells to Northern Natural Gas Company, Consolidated Gas Utilities Company and Permian Basin Pipe Line Company; also sales are made to Texas Gas Production Corporation for resale to El Paso Natural Gas Company. The natural gas so purchased by Northern Natural Gas Company, Consolidated Gas Utilities Company, Permian Basin Pipe Line Company and El Paso Natural Gas Company is transported in interstate commerce and resold for ultimate public consumption by each of them.

This matter is one that should be disposed of as promptly as possible under the applicable rules and regulations, and to that end:

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by sections 7 and 15 of the Natural Gas Act, and the Commission's rules of practice and procedure, a hearing will be held on January 13, 1956, at 9:30 a. m., e. s. t., in a hearing room of the Federal Power Commission, 441 G Street NW., Washington, D. C., concerning the matters involved in and the issues presented by such application: *Provided, however,* That the Commission may, after a non-contested hearing, dispose of the proceedings pursuant to the provisions of section 1.30 (c) (1) or (c) (2) of the Commission's rules of practice and procedure. Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicant to appear or be represented at the hearing.

Protests or petitions to intervene may be filed with the Federal Power Commission, Washington 25, D. C., in accordance with the rules of practice and procedure (18 CFR 1.8 or 1.10) on or before January 6, 1956. Failure of any party to appear at and participate in the hearing shall be construed as waiver of and concurrence in omission herein of the intermediate decision procedure in cases where a request therefor is made.

[SEAL] LEON M. FUQUAY,
Secretary.

[F. R. Doc. 55-10175; Filed, Dec. 19, 1955; 8:50 a. m.]

[Project No. 731]

P. E. HARRIS AND CO. AND ORGANIZED VILLAGE OF KAKE, ALASKA

NOTICE OF ORDER APPROVING TRANSFER OF LICENSE (MINOR)

DECEMBER 14, 1955.

Notice is hereby given that on November 30, 1955, the Federal Power Commission issued its order adopted November 23, 1955, approving transfer of license (Minor) in the above-entitled matter.

[SEAL] LEON M. FUQUAY,
Secretary.

[F. R. Doc. 55-10184; Filed, Dec. 19, 1955; 8:52 a. m.]

[Docket No. G-6749 etc.]

DOUGLAS WHITAKER ET AL.

NOTICE OF APPLICATIONS AND DATE OF HEARING

DECEMBER 14, 1955.

In the matters of Douglas Whitaker, Docket No. G-6749; Sid Richardson Gasoline Co., Docket No. G-6751; Ojai O & G Corporation, Docket No. G-6752; Sun Oil Company, Docket Nos. G-6833 to G-6839 incl., and G-6889; Houston Oil Company of Texas, Docket No. G-6849; Beaver Lodge Oil Corporation, Docket No. G-6886; J. R. Howe and G. D. Beauchamp, Docket No. G-6938; Pecos Company, Docket No. G-6943.

There were filed on November 30, 1954, with the Federal Power Commission applications as hereinafter specified.

Docket No.; Address; Location of Field; Buyer

G-6749; Shreveport, Louisiana; Sibley Field, Webster Parish, Louisiana; Arkansas-Louisiana Gas Company.

G-6751; Fort Worth, Texas; Keystone Field, Winkler County, Texas; El Paso Natural Gas Company.

G-6752; Fort Worth, Texas; Keystone Field, Winkler County, Texas; El Paso Natural Gas Company.

G-6833; Philadelphia, Pennsylvania (Address of Applicant Sun Oil Company, who has filed applications in Docket Nos. G-6833 to G-6839 incl. and G-6889; North Starks Field, Beauregard and Calcasieu Parishes, Louisiana; Transcontinental Gas Pipe Line Corporation.

G-6834; East Gibson Field, Terrebonne Parish, Louisiana; United Gas Pipe Line Company.

G-6835; Gist Field, Jasper and Newton Counties, Texas; Standard Oil Company of Texas.

G-6836 and G-6838; Eagan Field, Acadia Parish, Louisiana; Transcontinental Gas Pipe Line Corporation.

G-6837; Midland, Grand Chenier, and Hog Bayou Fields, Acadia Parish, Louisiana; Tennessee Gas Transmission Company.

G-6839; Hankamer, Gilbert Ranch, North Winnie and Stowell Fields, Chambers, Jefferson, and Liberty Counties, Texas; Texas Eastern Transmission Corporation.

G-6889; Eugene Island Field, Louisiana; United Gas Pipe Line Company.

G-6849; Houston, Texas; Koontz Field, Victoria County, Texas; United Gas Pipe Line Company.

G-6886; Dallas, Texas; San Juan Basin Area, San Juan and Rio Arriba Counties, New Mexico; El Paso Natural Gas Company.

G-6938; San Antonio, Texas; Kelsey Field, Starr County, Texas; Sun Oil Company.

G-6943; Lubbock, Texas; Benedum, Tex Harvey, and Santa Rosa Fields, Upton, Midland and Pecos County, Texas; El Paso Natural Gas Company.

Each has filed an application for a certificate of public convenience and necessity pursuant to section 7 of the Natural Gas Act, authorizing Applicants to render services as hereinbefore described, subject to the jurisdiction of the Commission, all as more fully represented in their respective applications which are on file with the Commission and open for public inspection.

Applicants produce and sell natural gas for transportation in interstate commerce for resale, as indicated above.

These related matters should be heard on a consolidated record and disposed of as promptly as possible under the applicable rules and regulations, and to that end:

Take further notice that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by sections 7 and 15 of the Natural Gas Act, and the Commission's rules of practice and procedure, a hearing will be held on January 20, 1956, at 9:30 a. m., e. s. t., in a hearing room of the Federal Power Commission, 441 G Street NW., Washington, D. C., concerning the matters involved in and the issues presented by such applications: *Provided, however,* That the Commission may, after a non-contested hearing dispose of the proceedings pursuant to the provisions of section 1.30 (c) (1) or (c) (2) of the Commission's rules of practice and procedure. Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicants to appear or be represented at the hearing.

Protests or petitions to intervene may be filed with the Federal Power Commission, Washington 25, D. C., in accordance with the rules of practice and procedure (18 CFR 1.8 or 1.10) on or before January 5, 1956. Failure of any party to appear at and participate in the hearing shall be construed as a waiver of and concurrence in omission herein of the intermediate decision procedure in cases where a request therefor is made.

[SEAL] LEON M. FUQUAY,
Secretary.

[F. R. Doc. 55-10176; Filed, Dec. 19, 1955; 8:51 a. m.]

[Docket No. E-6649]

MONTANA-DAKOTA UTILITIES CO.

NOTICE OF ORDER AUTHORIZING ISSUANCE OF PREFERRED STOCK

DECEMBER 14, 1955.

Notice is hereby given that on November 30, 1955, the Federal Power Commission issued its order adopted November 29, 1955, authorizing issuance of preferred stock in the above-entitled matter.

[SEAL] LEON M. FUQUAY,
Secretary.

[F. R. Doc. 55-10177; Filed, Dec. 19, 1955; 8:51 a. m.]

[Docket Nos. G-4454, G-9250]

HOPE NATURAL GAS CO.

NOTICE OF FINDINGS AND ORDER

DECEMBER 14, 1955.

Notice is hereby given that on November 29, 1955, the Federal Power Commission issued its findings and order adopted November 23, 1955, in the above-entitled matters, issuing certificate of public convenience and necessity and authorizing abandonment of service to Carnegie Natural Gas Company.

[SEAL] LEON M. FUQUAY,
Secretary.

[F. R. Doc. 55-10178; Filed, Dec. 19, 1955; 8:51 a. m.]

[Docket No. G-9116 etc.]

UNITED GAS PIPE LINE CO. ET AL.

NOTICE OF FINDINGS AND ORDERS

DECEMBER 14, 1955.

In the matters of United Gas Pipe Line Company, Docket No. G-9116; Transcontinental Gas Pipe Line Corporation, Docket No. G-9117; Summers Oil and Gas Company, Docket No. G-9139; Price Gas Company, Docket No. G-9245.

Notice is hereby given that on November 29, 1955, the Federal Power Commission issued its findings and orders adopted November 23, 1955, issuing certificates of public convenience and necessity in the above-entitled matters.

[SEAL] LEON M. FUQUAY,
Secretary.

[F. R. Doc. 55-10179; Filed, Dec. 19, 1955; 8:51 a. m.]

[Docket No. G-8588]

THOMAS A. KENDALL ET AL.

NOTICE OF APPLICATION AND DATE OF HEARING

DECEMBER 14, 1955.

In the matters of Thomas A. Kendall, E. Allen Phipps, George Ogle, Marton L. Fearey and wife, Mary S. Fearey, Charles Cooley, Maxwell M. Belding, Thatcher W. Worthen, W. N. Swery, Robert Fulton Sears, Olaf Mineral Development Corp., Joseph W. Worthen, Sidney A. Stewart, William H. Winn, Earl Smith, Joe Bart Moore.

Take notice that Thomas A. Kendall, an individual whose address is 214 Travis Building, San Antonio 5, Texas, as operator of the hereinafter described lease and agent for the remaining parties as captioned above, filed, on March 15, 1955, for and on behalf of himself and aforesaid parties (Applicants) an application for certificates of public convenience and necessity pursuant to section 7 of the Natural Gas Act, authorizing Applicants to render service as hereinafter described, subject to the jurisdiction of the Commission, all as more fully represented in the application which is on file with the Commission and open for public inspection.

Applicants propose to sell natural gas in interstate commerce from production of 170 acres of a lease, Blancona Field, East Central Bee County, Texas, to United Piipe Line Company for resale.

This matter is one that should be disposed of as promptly as possible under the applicable rules and regulations and to that end:

Take further notice, that, pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Power Commission by sections 7 and 15 of the Natural Gas Act, and the Commission's rules of practice and procedure, a hearing will be held on Monday, January 23, 1956, at 9:30 a. m., e. s. t, in a Hearing Room of the Federal Power Commission, 441 G Street, NW., Washington, D. C., concerning the matters involved in and the issues presented by such application: *Provided, however,* That the Commission may, after a non-contested hearing, dispose of the proceedings pursuant to the provisions of section 1.30 (c) (1) or (c) (2) of the Commission's rules of practice and procedure. Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for Applicants to appear or be represented at the hearing.

Protests or petitions to intervene may be filed with the Federal Power Commission, Washington 25, D. C., in accordance with the rules of practice and procedure (18 CFR 1.8 or 1.10) on or before January 2, 1956. Failure of any party to appear at and participate in the hearing shall be construed as waiver of and concurrence in omission herein of the intermediate decision procedure in cases where a request therefor is made.

[SEAL] LEON M. FUQUAY,
Secretary.

[F. R. Doc. 55-10180; Filed, Dec. 19, 1955; 8:51 a. m.]

SECURITIES AND EXCHANGE COMMISSION

[File No. 24D-1436]

TRANS-CONTINENTAL URANIUM CORP.

ORDER TEMPORARILY SUSPENDING EXEMPTION, STATEMENT OF REASONS THEREFOR, AND NOTICE OF OPPORTUNITY FOR HEARING

DECEMBER 13, 1955.

I. Trans-Continental Uranium Corporation, a Nevada corporation, 358 South Third East Street, Salt Lake City, Utah, having filed with the Commission on October 1, 1954, a notification on Form 1-A, and subsequently filed amendments thereto, relating to a proposed public offering of 3,000,000 shares of common stock, par value 10 cents, at 10 cents per share for the purpose of obtaining an exemption from the registration requirements of the Securities Act of 1933, as amended, pursuant to the provisions of section 3 (b) thereof and Regulation A promulgated thereunder; and:

II. A. The Commission having reasonable cause to believe that the terms and conditions of Regulation A have not been complied with in that the company has failed to file on Form 2-A reports of sales as required by Rule 224 of Regulation A;

B. The Commission having been advised that Justin Steppler, Inc., a principal underwriter of the securities offered, and Beverly I. Steppler, a director of the issuer, have been permanently enjoined by the New York State Supreme Court, County of New York, from engaging in the business of acting as a broker or dealer in securities in the State of New York.

III. *It is ordered,* Pursuant to Rule 223 (a) of the General Rules and Regulations under the Securities Act of 1933 that the exemption under Regulation A be, and it hereby is, temporarily suspended.

Notice is hereby given that any person having any interest in the matter may file with the Secretary of the Commission a written request for a hearing; that, within 20 days after receipt of such request, the Commission will, or at any time upon its own motion may, set the matter down for hearing at a place to be designated by the Commission for the purpose of determining whether this order of suspension should be vacated or made permanent, without prejudice, however, to the consideration and presentation of additional matters at the hearing; and that notice of the time and place of said hearing will be promptly given by the Commission.

It is further ordered, That this order and notice shall be served upon Trans-Continental Uranium Corporation, 358 South Third East Street, Salt Lake City, Utah, Justin Steppler, Inc., 15 Exchange Place, Jersey City 2, New Jersey and Registrar and Transfer Co., 15 Exchange Place, Jersey City 2, New Jersey, personally or by registered mail or confirmed telegraphic notice, and shall be published in the FEDERAL REGISTER.

By the Commission.

[SEAL] ORVAL L. DUBOIS,
Secretary.

[F. R. Doc. 55-10143; Filed, Dec. 19, 1955; 8:45 a. m.]

[24D-1328]

ZENITH URANIUM & MINING CORP.

ORDER TEMPORARILY SUSPENDING EXEMPTION, STATEMENT OF REASONS THEREFOR, AND NOTICE OF OPPORTUNITY FOR HEARING

DECEMBER 13, 1955.

I. Zenith Uranium & Mining Corp., 351 South State Street, Salt Lake City, Utah, having filed with the Commission on July 12, 1954, a Notification on Form 1-A and an offering circular, and having subsequently filed amendments thereto on July 30 and August 2, 1954, relating to a proposed public offering of 300,000 shares of 1 cent par common stock at $1 per share, for the purpose of obtaining an exemption from the registration requirements of the Securities Act of 1933, as amended, pursuant to the provisions of section 3 (b) thereof and Regulation A promulgated thereunder; and,

II. A. The Commission having reasonable cause to believe that the terms and conditons of Regulation A have not been complied with in that the issuer has failed to file reports of sales on Form 2-A as required by Rule 224; and,

B. The Commission having been advised that a consent order was entered on October 31, 1955, in the United States District Court for the District of Massachusetts, permanently enjoining Daniel M. Sheehan, Jr., doing business as Sheehan & Company, a director and promoter of the company, who is also the principal underwriter of the securities proposed to be offered hereunder, from further violations of sections 10 (b), 15 (c) (1) and 17 (a) of the Securities Exchange Act of 1934 and the Rules and Regulations promulgated thereunder, in connection with the purchase and sale of any security.

III. *It is ordered,* Pursuant to Rule 223 (a) of the general rules and regulations under the Securities Act of 1933, as amended, that the exemption under

Regulation A be, and it hereby is, temporarily suspended.

Notice is hereby given that any person having any interest in the matter may file with the Secretary of the Commission a written request for a hearing; that, within 20 days after receipt of such request, the Commission will, or at any time upon its own motion may, set the matter down for hearing at a place to be designated by the Commission for the purpose of determining whether this order of suspension should be vacated or made permanent, without prejudice, however, to the consideration and presentation of additional matters at the hearing; and that notice of the time and place for said hearing will be promptly given by the Commission.

It is further ordered, That this order and notice shall be served upon Zenith Uranium & Mining Corp. and Daniel M. Sheehan, Jr., doing business as Sheehan & Company, 79 Milk Street, Boston, Massachusetts, personally or by registered mail or by confirmed telegraphic notice, and shall be published in the FEDERAL REGISTER.

By the Commission.

[SEAL] ORVAL L. DUBOIS,
Secretary.

[F. R. Doc. 55-10144; Filed, Dec. 19, 1955; 8:45 a. m.]

[File No. 27-61]

VIGORELLI OF CANADA LTD.

ORDER TEMPORARILY SUSPENDING EXEMPTION, STATEMENT OF REASONS THEREFOR, AND NOTICE OF OPPORTUNITY FOR HEARING

DECEMBER 13, 1955.

Vigorelli of Canada Ltd. having filed with the Commission on August 9, 1954, for the purpose of obtaining an exemption from the registration requirements of the Securities Act of 1933, as amended, pursuant to the provisions of section 3 (b) thereof and Regulation D thereunder, a Notification on Form 1-D relating to a proposed offering of 96,770 shares of Common Shares ($1 Par Value) and 96,770 shares of 8 percent Cumulative Redeemable Preferred Shares ($2 Par Value) for an aggregate public offering price of $299,987;

The Commission having been advised that the terms and conditions of said Regulation D have not been complied with in that Vigorelli of Canada Ltd. has failed to file a report on Form 2-D for the six months period following the commencement of the offering as required by Rule 510 of Regulation D and has ignored requests by the Commission's staff for the filing of such report:

It is ordered, Pursuant to Rule 509 (a) of the general rules and regulations under the Securities Act of 1933, as amended, that the exemption of Vigorelli of Canada Ltd. under section 3 (b) and Regulation D be, and it hereby is, temporarily suspended.

Notice is hereby given that any person having any interest in the matter may file with the Secretary of the Commission a written request for a hearing; that, within 20 days after receipt of such request, the Commission will, or at any time upon its own motion may, set the matter down for hearing at a place to be designated by the Commission for the purpose of determining whether this order of suspension should be vacated or made permanent, without prejudice, however, to the consideration and presentation of additional matters at the hearing; and that notice of the time and place for said hearing will be promptly given by the Commission.

It is further ordered, That this order and notice shall be served upon Vigorelli of Canada Ltd., Crisona Brothers, B. Fennekohl & Co. and Toronto General Trusts Corporation personally or by registered mail or by confirmed telegraphic notice, and shall be published in the FEDERAL REGISTER.

By the Commission.

[SEAL] ORVAL L. DUBOIS,
Secretary.

[F. R. Doc. 55-10145; Filed, Dec. 19, 1945; 8:45 a. m.]

[File No. 812-976]

AMERICAN RESEARCH AND DEVELOPMENT CORP. AND PAUL VALVE CORP.

NOTICE OF FILING REQUESTING ORDER EXEMPTING PROPOSED TRANSACTION BETWEEN AFFILIATES

DECEMBER 14, 1955.

Notice is hereby given that American Research and Development Corporation ("Research"), a registered closed-end nondiversified investment company, has filed an application pursuant to section 17 (b) of the Investment Company Act of 1940 ("act") seeking an order exempting the proposed transaction, described below, from the prohibition contained in section 17 (a) (2) of the act.

Paul Valve Corporation ("Paul"), a New Jersey corporation organized in 1947, is engaged in the sale of valves for use in pulp mills, chemical process plants, product pipelines and other industrial applications.

Pursuant to a plan of reorganization consummated in April 1955, Paul exchanged new 10 cent par value common stock for all of its previously outstanding securities. Research received 22,621 shares of new common stock of Paul (22.6 percent of the new stock outstanding) in exchange for $62,000 principal amount of debentures and 26,040 shares of old common stock of Paul which it then held. This transaction was exempted by order of the Commission dated April 14, 1955 (Investment Company Act Release No. 2133).

It is stated that notwithstanding the reorganization Paul's business and credit has not improved; operations for the first four months of the fiscal year beginning May 1, 1955, resulted in a loss of $1,545. It is also stated that there is no working capital and no interest among stockholders sufficient to produce the needed working capital. Book value of the common stock of Paul as of September 30, 1955, amounted to $15,395 of which approximately $3,400 is applicable to Research's 22.6 percent stock interest. Paul's operations have been unprofitable in four of the last five years.

Research now proposes to sell its 22,661 shares of common stock of Paul to Alexander D. Harvey, President, director, and holder, together with his wife, of 9,000 shares of the common stock of Paul (equivalent to 9 percent of the stock outstanding), for an aggregate consideration of $6,460 or approximately $0.285 per share.

Research's cost of the stock is $64,604 measured by reference to the cost of $62,000 for the debentures and $2,604 paid for the old common stock surrendered in exchange for 22,661 shares of new common stock of Paul pursuant to the reorganization referred to above. Thus the $6,460 to be received by Research is approximately 10 percent of Research's original cost, but is substantially in excess of the book value of Research's interest of $3,480 in Paul as at September 30, 1955.

Generally speaking, section 17 (a) (2) of the act prohibits an affiliated person of an affiliated person of a registered investment company from purchasing any securities from such registered investment company, with one exception not applicable here, unless the Commission upon application pursuant to section 17 (b) of the act, grants an exemption from section 17 (a) (2) of the act after finding that the terms of the proposed transaction, including the consideration to be paid, are reasonable and fair and do not involve overreaching on the part of any person concerned, that the proposed transaction is consistent with the policy of each registered investment company concerned, as recited in its registration statement and reports filed under the act, and is consistent with the general purposes of the act.

By virtue of his position as an officer, director, and as a holder of more than 5 percent of the stock of Paul, Harvey is an affiliated person of Paul under the act; Paul is also an affiliated person of Research because of the latter's 22.6 percent stock interest in Paul; therefore, since Harvey is an affiliated person of an affiliated person (Paul) of a registered investment company (Research), the proposed transaction is prohibited by section 17 (a) (2) of the act unless exempted by the Commission pursuant to section 17 (b) of the act.

Research asserts that the proposed transaction was negotiated at arm's length and that except as stated above, Research is not affiliated directly or indirectly with Harvey.

Notice is further given that any interested person may, not later than December 27, 1955, at 5:30 p. m., submit to the Commission in writing any facts bearing upon the desirability of a hearing on the matter and may request that a hearing be held, such request stating the nature of his interest, the reasons for such request and the issues, if any, of fact or law proposed to be controverted, or he may request that he be notified if the Commission should order a hearing thereon. Any such communication or request should be addressed: Secretary, Securities and Exchange Commission, Washington 25, D. C. At any time after said date, the application may be granted as provided in Rule N-5 of the rules and regulations promulgated under the act.

By the Commission.

[SEAL] ORVAL L. DUBOIS,
Secretary.

[F. R. Doc. 55-10146; Filed, Dec. 19, 1955; 8:46 a. m.]

[File No. 70-3428]

GENERAL PUBLIC UTILITIES CORP. AND ASSOCIATED ELECTRIC CO.

NOTICE OF FILING OF APPLICATION-DECLARATION REGARDING DISSOLUTION OF INTERMEDIATE HOLDING COMPANY, ACQUISITION OF ITS ASSETS BY TOP HOLDING COMPANY, AND CAPITAL CONTRIBUTION TO SUBSIDIARY OPERATING COMPANY

DECEMBER 14, 1955.

Notice is hereby given that General Public Utilities Corporation ("GPU") and Associated Electric Company ("Aelec"), both registered holding companies have filed with the Commission an application-declaration pursuant to the Public Utility Holding Company Act of 1935 ("act") and have designated sections 9 (a), 10, 11, 12 (b), and 12 (c) of the act, and Rules U-42 and U-44 (c) promulgated thereunder, as applicable to the proposed transactions, which are summarized as follows:

GPU, a New York corporation, owns all of the outstanding securities (consisting of 400,000 shares of common stock) of Aelec, a Delaware corporation. It is proposed, if the Commission shall grant and permit to become effective the application-declaration in File No. 70-3050, relating to the proposed merger of Northern Pennsylvania Power Company into Pennsylvania Electric Company and modification of the Commission's order of December 28, 1951, in File No. 59-32 so as to permit retention in the GPU holding-company system of Northern Pennsylvania Power Company, that Aelec will be dissolved under the provisions of Delaware law and all its assets, subject to its liabilities, transferred to GPU. Aelec's principal assets consist of all the outstanding common stock of Pennsylvania Electric Company, all of the outstanding preferred and common stocks and $4,000,000 principal amount of debentures of Manila Electric Company ("Meralco") and all of the outstanding securities (consisting of 2,000 shares of common stock) of Escudero Electric Service Company ("Escudero"). The two companies last mentioned are public utility companies operating in the Philippines and have been granted exemption from certain provisions of the act pursuant to section 3 (b) thereof. It is proposed that, after the dissolution of Aelec and the aforementioned transfer of Aelec's assets to GPU, GPU will make a capital contribution to Meralco of all of the outstanding common stock of Escudero.

It is stated that no State or Federal commission, other than this Commission, has jurisdiction over any of the proposed transactions, but that the transfer from Aelec to GPU of all of the outstanding common stock of Meralco and Escudero, and the subsequent transfer by GPU to Meralco as a capital contribution of all of the outstanding common stock of Escudero, require the approval of the Public Service Commission of the Philippines.

Applicants-declarants stipulate and agree that the granting and permitting to become effective of the application-declaration and the carrying out of the transactions herein proposed shall not be deemed, in any manner, to modify or otherwise affect the Commission's orders, dated August 13, 1942, and December 28, 1951 in File No. 59-32, requiring the divestiture by GPU of its interest in Escudero and Meralco.

Applicants-declarants request that the Commission's order granting and permitting to become effective the application-declaration contain the recitals with respect to the transfer by Aelec to GPU of its assets requisite to meet the requirements of Sections 1081-1083, inclusive, of the Internal Revenue Code of 1954.

Notice is further given that any interested person may, not later than January 5, 1956, at 5:30 p. m., request the Commission in writing that a hearing be held on this matter, stating the nature of his interest, the reason for such request, and the issues of fact or law, if any, raised by such filing which he proposes to controvert, or he may request that he be notified if the Commission should order a hearing thereon. Any such request should be addressed: Secretary, Securities and Exchange Commission, Washington 25, D. C. At any time after said date, the application-declaration, as filed or as hereafter amended, may be granted and permitted to become effective as provided in Rule U-23 of the Rules and Regulations promulgated under the Act, or the Commission may grant exemption from its rules as provided in Rules U-20 (a) and U-100 or take such other action as it may deem appropriate.

By the Commisssion.

[SEAL] ORVAL L. DUBOIS,
Secretary.

[F. R. Doc. 55-10147; Filed, Dec. 19, 1955; 8:46 a. m.]

[File No. 70-3410]

GENERAL PUBLIC UTILITIES CORP. ET AL.

ORDER REGARDING AGREEMENT PROVIDING FOR ALLOCATION OF CONSOLIDATED FEDERAL INCOME TAX LIABILITIES

DECEMBER 14, 1955.

General Public Utilities Corporation, a registered holding company, and its subsidiary companies, Jersey Central Power & Light Company, Metropolitan Edison Company, New Jersey Power & Light Company, Northern Pennsylvania Power Company, The Waverly Electric Light and Power Company, Pennsylvania Electric Company, Blair Fuel Company, Nineveh Water Company, Brockway Light, Heat and Power Company, Employees Walfare Association, Inc., and Associated Electric Company, having filed a declaration with the Commission pursuant to section 12 (b) of the Public Utility Holding Company Act of 1935 ("act") and Rule U-45 (a) promulgated thereunder regarding a certain proposed transaction, which is summarized as follows:

Declarants propose to enter into an agreement governing the allocation among said companies of the consolidated Federal income tax liability of such group of companies. It is stated that the proposed agreement does not comply with the exemption provisions of Rule U-45 (b) (6) in that it provides that (i) commencing with the tax return for 1954 and thereafter, a company which elects to claim a deduction for accelerated amortization of emergency facilities, as distinct from normal depreciation deductions, shall have allocated to it the entire tax benefits, and bear the entire tax burdens, attributable to such deduction, and (ii) commencing with the year 1955 and thereafter, a company which elects to claim a foreign tax credit shall have allocated to it the entire tax benefits attributable to such credit.

The declaration states that no State or Federal regulatory body, other than this Commission, has jurisdiction with respect to the proposed transaction.

Notice of the filing of said declaration having been given in the manner prescribed by Rule U-23, and no hearing having been requested of or ordered by the Commission; and the Commission finding that the applicable provisions of the act and of the rules thereunder are satisfied and that the declaration should be permitted to become effective forthwith:

It is ordered, Pursuant to Rule U-23 and the applicable provisions of the act, that said declaration be, and the same hereby is, permitted to become effective forthwith, subject to the terms and conditions set forth in Rule U-24.

By the Commission.

[SEAL] ORVAL L. DUBOIS,
Secretary.

[F. R. Doc. 55-10148; Filed, Dec. 19, 1955; 8:46 a. m.]

DEPARTMENT OF JUSTICE

Office of Alien Property

HYALOS S. A.

NOTICE OF INTENTION TO RETURN VESTED PROPERTY

Pursuant to section 32 (f) of the Trading With the Enemy Act, as amended, notice is hereby given of intention to return, on or after 30 days from the date of publication hereof, the following property, subject to any increase or decrease resulting from the administration thereof prior to return, and after adequate provision for taxes and conservatory expenses:

Claimant, Claim No., Property, and Location

Hyalos S. A., a/k/a Hyalos A. G., Bahnhof Strasse 23, Zug, Switzerland; Claim No. 62087, Vesting Order No. 17976; $2,988.00 in the Treasury of the United States.

Executed at Washington, D. C., on December 12, 1955.

For the Attorney General.

[SEAL] PAUL V. MYRON,
Deputy Director,
Office of Alien Property.

[F. R. Doc. 55-10173; Filed, Dec. 19, 1955; 8:50 a. m.]

ANGELA VERCELLI ET AL.

NOTICE OF INTENTION TO RETURN VESTED PROPERTY

Pursuant to section 32 (f) of the Trading With the Enemy Act, as amended, notice is hereby given of intention to return, on or after 30 days from the date of publication hereof, the following property, subject to any increase or decrease resulting from the administration thereof prior to return, and after adequate provision for taxes and conservatory expenses:

Claimant, Claim No., Property, and Location

Angela Vercelli, $148.01 in the Treasury of the United States. Anita Vercelli Gavazza, $148.01 in the Treasury of the United States. Cecilia Vercelli, $148.01 in the Treasury of the United States. Felice Vercelli, $148.01 in the Treasury of the United States. Marcorengo, Turin, Italy. Louis Vercelli, $74 in the Treasury of the United States. Ceaser Vercelli, $74 in the Treasury of the United States. Chicago, Illinois, Claims No. 34674 and 42349. John Vercelli, Executor of the Estate of Michele Vercelli, deceased, $185.01 in the Treasury of the United States. Pitcairn, Pennsylvania, Claim No. 42769, Carlo Vercelli, $185.01 in the Treasury of the United States. Turtle Creek Boro, Pennsylvania, Claim No. 42770, Vesting Order No. 1662.

Executed at Washington, D. C., on December 12, 1955.

For the Attorney General.

[SEAL] PAUL V. MYRON,
Deputy Director,
Office of Alien Property.

[F. R. Doc. 55-10174; Filed, Dec. 19, 1955; 8:50 a. m.]

INTERSTATE COMMERCE COMMISSION

FOURTH SECTION APPLICATIONS FOR RELIEF

DECEMBER 15, 1955.

Protests to the granting of an application must be prepared in accordance with Rule 40 of the General Rules of Practice (49 CFR 1.40) and filed within 15 days from the date of publication of this notice in the FEDERAL REGISTER.

LONG-AND-SHORT HAUL

FSA No. 31423: *Paint and materials to Missouri River crossings.* Filed by W. J. Prueter, Agent, for interested rail carriers. Rates on paint, paint material and related articles, carloads from Chicago, Kankakee, and Rockford, Ill., Milwaukee, Racine, and Waxdale, Wis., Minneapolis, Minnesota Transfer, and St. Paul, Minn., and St. Louis, Mo., to specified points in Iowa, Kansas, Nebraska, and South Dakota on or near the Missouri River.

Grounds for relief: Circuitous routes.

Tariff: Supplement 49 to Agent Prueter's I. C. C. A-4038.

FSA No. 31424: *Iron and steel articles to Eastern Canadian Ports.* Filed by H. R. Hinsch, Agent, for interested rail carriers. Rates on iron and steel articles, carloads, also billets and articles taking same rates, carloads from specified points in central territory and in trunk-line arbitrary east of Pittsburgh, Pa., to specified eastern Canadian ports in the Provinces of New Brunswick, Nova Scotia, and Quebec.

Grounds for relief: Maintenance of port rate relations with north Atlantic seaboard ports in the United States, and circuitous routes.

Tariff: Supplement 78 to Agent Hinsch's I. C. C. 4350 and seven other tariffs.

FSA No. 31425: *Scrap paper—Florida points to the Southwest.* Filed by F. C. Kratzmeir, Agent, for interested rail carriers. Rates on paper, scrap or waste, other than sensitized and excelsior paper, straight or mixed carloads from Jacksonville, South Jacksonville, and Tampa, Fla., to Dallas, Tex., Shreveport, La., and Pryor (including Oklahoma Ordnance Works), Okla.

Grounds for relief: Short-line distance formula and circuitous routes.

Tariff: Supplement 143 to Agent Kratzmeir's I. C. C. 4090 and two other tariffs.

FSA No. 31426: *Lumber—West Virginia to North Carolina.* Filed by R. E. Boyle, Jr., Agent, for interested rail carriers. Rates on lumber, carloads from specified points in West Virginia to Greensboro, Mt. Airy, and Sanford, N. C.

Grounds for relief: Circuitous routes.

Tariff: Supplement 98 to Agent Spaninger's I. C. C. 1297.

FSA No. 31427: *Fertilizer compounds—Arkansas and Louisiana to the South.* Filed by F. C. Kratzmeir, Agent, for interested rail carriers. Rates on fertilizer compounds and related articles, carloads from Kay, Ark., and Bernice, La., to specified points in Alabama, Florida, Georgia, Kentucky, Louisiana (east of the Mississippi River), North Carolina, South Carolina, Tennessee, and West Virginia, also to Cincinnati, Ohio and Helena, Ark.

Grounds for relief: Short-line distance formula and circuity.

Tariff: Supplement 104 to Agent Kratzmeir's I. C. C. 4112.

FSA No. 31428: *Billets—Chicago, Ill., and Steelton, Ky., to Louisiana and Texas.* Filed by F. C. Kratzmeir, Agent, for interested rail carriers. Rates on iron and steel billets, other than copper clad, carloads from Chicago, Ill., and district points, and Steelton, Ky., to Doyline and Shreveport, La., and Longview, Tex.

Grounds for relief: Barge-rail competition and circuity.

Tariff: Supplement 24 to Agent Kratzmeir's I. C. C. 4170.

FSA No. 31429: *Salt—Louisiana to Alabama and Mississippi.* Filed by F. C. Kratzmeir, Agent, for interested rail carriers. Rates on mine run salt, in bulk, carloads, from Anse La Butte, Avery Island, Carla, Jefferson Island, Weeks, and Winfield, La., to Listerhill, Evans City, Emco, Sheffield, and Tuscumbia, Ala., and other specified points in Alabama and Mississippi.

Grounds for relief: Barge competition and circuity.

Tariff: Supplement 59 to Agent Kratzmeir's I. C. C. 3903.

FSA No. 31430: *Grain—Fitzgerald, Ga., to Wilmington, N. C.* Filed by R. E. Boyle, Jr., Agent, for interested rail carriers. Rates on grain, namely, barley, corn, oats, rye, soybeans, and wheat, in bulk, straight carloads from Fitzgerald, Ga., to Wilmington, N. C., for export, and for trans-shipment via water to coastal points north of Hampton Roads, Va.

Grounds for relief: Circuitous route.

Tariff: Supplement 113 to Agent C. A. Spaninger's I. C. C. 1325.

FSA No. 31431: *Substituted motor service—M-K-T System Lines.* Filed by Middlewest Motor Freight Bureau, Agent, for interested rail and motor carriers. Rates on various commodities in highway trailers on railroad flat cars, also empty trailers on such cars between St. Louis, Mo., on one hand, and Oklahoma City, Okla., on the other; also between Kansas City, Kans., on one hand, and Oklahoma City and Tulsa, Okla., on the other; also between St. Louis, Mo., or Kansas City, Kans., on one hand, and Dallas and Ft. Worth, Tex., on the other.

Grounds for relief: Motor truck competition.

Tariff: Supplement 32 to Middlewest Motor Freight Bureau MF-I. C. C. 223.

FSA No. 31432: *Motor-rail rates—Missouri-Kansas-Texas R. R. et al.* Filed by Middlewest Motor Freight Bureau, Agent, for interested rail and motor carriers. Rates on various commodities in trailers, transported on railroad flat cars between points in Kansas, Missouri, Oklahoma, and Texas.

Grounds for relief: Motor carrier competition.

Tariff: Supplement 32 to Middlewest Motor Freight Bureau tariff MF-I. C. C. No. 223.

FSA No. 31433: *Motor-rail rates—Chicago Great Western Ry. Co. et al.* Filed by Middlewest Motor Freight Bureau, Agent, for interested rail and motor carriers. Rates on various commodities in trailers, transported on railroad flat cars between Chicago, Ill., on the one hand, and Council Bluffs, or Des Moines, Iowa, on the other.

Grounds for relief: Motor carrier competition.

Tariff: Supplement No. 32 to Middlewest Motor Freight Bureau tariff MF-I. C. C. No. 223.

FSA No. 31434: *Motor-rail rates—Missouri-Kansas-Texas R. R. et al.* Filed by Middlewest Motor Freight Bureau, for interested rail and motor carriers. Rates on various commodities in trailers, transported on railroad flat cars between St. Louis, Mo., on the one hand, and Muskogee, Okla., on the other.

Grounds for relief: Motor carrier competition.

Tariff: Supplement 32 to Middlewest Motor Freight Bureau tariff MF-I. C. C. 223.

FSA No. 31435: *Automobile bodies from Michigan to the East.* Filed by H. R. Hinsch, Agent, for interested rail carriers. Rates on automobile bodies, freight or passenger, carloads from Ionia and Pontiac, Mich, to Metuchen, N. J., Framingham, Mass., and Wilmington, Del.

Grounds for relief: Carrier competition and circuity.

By the Commission.

[SEAL] HAROLD D. McCOY,
Secretary.

[F. R. Doc. 55-10156; Filed, Dec. 19, 1955; 8:48 a. m.]

PART II

FEDERAL REGISTER

VOLUME 20 NUMBER 246

Washington, Tuesday, December 20, 1955

TITLE 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

REPUBLICATION OF REGULATIONS

Chapter I of Title 21 is republished, reading as set forth below. In this republication minor editorial changes have been made and Parts 135, 145, 155, 170, 175, 185, and 196 have been redesignated as Parts 9, 165, 85, 281, 285, 290, and 4, respectively.

Dated: December 15, 1955.

[SEAL] GEO. P. LARRICK,
Commissioner of Food and Drugs.

Subchapter A—General

Part
1 Regulations for the enforcement of the Federal Food, Drug, and Cosmetic Act.
3 Statements of general policy or interpretation.
4 Official records and information.
9 Color certification.

Subchapter B—Food and Food Products

10 General regulations relating to definitions and standards for food.
14 Cacao products; definitions and standards of identity.
15 Cereal flours and related products; definitions and standards of identity.
16 Alimentary pastes; definitions and standards of identity.
17 Bakery products; definitions and standards of identity.
18 Milk and cream; definitions and standards of identity.
19 Cheeses; processed cheeses; cheese foods; cheese spreads; and related foods; definitions and standards of identity.
25 Dressings for foods.
27 Canned fruits; definitions and standards of identity; quality; and fill of container.
29 Fruit butters, fruit jellies, fruit preserves, and related products; definitions and standards of identity.
36 Shellfish; definitions and standards of identity; fill of container.
42 Eggs and egg products; definitions and standards of identity.
45 Oleomargarine, margarine; definitions and standard of identity.
51 Canned vegetables; definitions and standards of identity; quality; and fill of container.

This issue is divided into two parts, Part II of which contains a republication of Title 21, Chapter I, of the Code of Federal Regulations.

Part
53 Tomato products; definitions and standards of identity; quality; and and fill of container.
85 Seafood inspection.
120 Tolerances and exemptions from tolerances for pesticide chemicals in or on raw agricultural commodities.
125 Label statements concerning dietary properties of food purporting to be or represented for special dietary uses.

Subchapter C—Drugs

130 Drugs exempted from prescription-dispensing requirements of section 503 (b) (1) (C) of the Federal Food, Drug, and Cosmetic Act.
141a Penicillin and penicillin-containing drugs; tests and methods of assay.
141b Streptomycin (or dihydrostreptomycin) and streptomycin- (or dihydrostreptomycin-) containing drugs; tests and methods of assay.
141c Chlortetracycline (or tetracycline) and chlortetracycline- (or tetracycline-) containing drugs; tests and methods of assay.
141d Chloramphenicol and chloramphenicol-containing drugs; tests and methods of assay.
141e Bacitracin and bacitracin-containing drugs; tests and methods of assay.
146 General regulations for the certification of antibiotic and antibiotic-containing drugs.
146a Certification of penicillin and penicillin-containing drugs.
146b Certification of streptomycin (or dihydrostreptomycin) and streptomycin- (or dihydrostreptomycin-) containing drugs.
146c Certification of chlortetracycline (or tetracycline) and chlortetracycline- (or tetracycline-) containing drugs.
146d Certification of chloramphenicol and chloramphenicol-containing drugs.
146e Certification of bacitracin and bacitracin-containing drugs.
164 Certification of batches of drugs composed wholly or partly of insulin.
165 Certain chemical derivatives of substances named in section 502 (d) of the Federal Food, Drug, and Cosmetic Act designated as habit forming.

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Subchapter A—General

PART 1—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

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GENERAL

§ 1.1 *General regulation.* (a) The provisions of regulations promulgated under the act with respect to the doing of any act shall be applicable also to the causing of such act to be done.

(b) The definitions and interpretations of terms contained in section 201 of the act shall be applicable also to such terms when used in regulations promulgated under the act.

(Sec. 701 (a), 52 Stat. 1055; 21 U.S.C. 371 (a))

DEFINITIONS

AUTHORITY: §§ 1.2 and 1.3 issued under sec. 701 (a), 52 Stat. 1055; 21 U. S. C. 371 (a). Statutory provisions interpreted or applied are cited to text in parentheses.

§ 1.2 *Labeling; definition.* Labeling includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce.

(Sec. 201 (m), 52 Stat. 1041; 21 U. S. C. 321 (m))

§ 1.3 *Difference of opinion among experts.* The existence of a difference of opinion, among experts qualified by scientific training and experience, as to the truth of a representation made or suggested in the labeling is a fact (among other facts) the failure to reveal which may render the labeling misleading, if there is a material weight of opinion contrary to such representation.

(Sec. 201 (n), 52 Stat. 1041; 21 U. S. C. 321 (n))

PROHIBITED ACTS AND PENALTIES

AUTHORITY: §§ 1.4 to 1.6 issued under sec. 701 (a), 52 Stat. 1055; 21 U. S. C. 371 (a). Statutory provisions interpreted or applied are cited to text in parentheses.

§ 1.4 *Guaranty.* In case of the giving of a guaranty or undertaking referred to in section 303 (c) (2) or (3) of the act, each person signing such guaranty or undertaking shall be considered to have given it.

(Sec. 301 (h), 52 Stat. 1042; 21 U. S. C. 331 (h))

§ 1.5 *Guaranty; definition, and suggested forms.* (a) A guaranty or undertaking referred to in section 303 (c) (2) of the act may be:

(1) Limited to a specific shipment or other delivery of an article, in which case it may be a part of or attached to the invoice or bill of sale covering such shipment or delivery, or

(2) General and continuing, in which case, in its application to any shipment or other delivery of an article, it shall be considered to have been given at the date such article was shipped or delivered by the person who gives the guaranty or undertaking.

(b) The following are suggested forms of guaranty or undertaking under section 303 (c) (2) of the act:

(1) Limited form for use on invoice or bill of sale.

(Name of person giving the guaranty or undertaking) hereby guarantees that no article listed herein is adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, or is an article which may not, under the provisions of section 404 or 505 of the act, be introduced into interstate commerce.

(Signature and post-office address of person giving the guaranty or undertaking)

(2) General and continuing form.

The article comprising each shipment or other delivery hereafter made by (name of person giving the guaranty or undertaking) to, or on the order of (name and post-office address of person to whom the guaranty or undertaking is given) is hereby guaranteed, as of the date of such shipment or delivery, to be, on such date, not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act, and not an article which may not, under the provisions of section 404 or 505 of the act, be introduced into interstate commerce.

(Signature and post-office address of person giving the guaranty of undertaking)

(c) The application of a guaranty or undertaking referred to in section 303 (c) (2) of the act to any shipment or other delivery of an article shall expire when such article, after shipment or delivery by the person who gave such guaranty or undertaking, becomes adulterated or misbranded within the meaning of the act, or becomes an article which may not, under the provisions of section 404 or 505 of the act, be introduced into interstate commerce.

(d) A guaranty or undertaking referred to in section 303 (c) (3) of the act shall state that the shipment or other delivery of coal-tar color covered thereby was manufactured by a signer thereof. It may be a part of or attached to the invoice or bill of sale covering such color. If such shipment or delivery is from a foreign manufacturer, such guaranty or undertaking shall be signed by such manufacturer and by an agent of such manufacturer who resides in the United States.

(e) The following are suggested forms of guaranty or undertaking under section 303 (c) (3) of the act:

(1) For domestic manufacturers.

(Name of manufacturer) hereby guarantees that all coal-tar colors listed herein were manufactured by him, and are from batches certified in accordance with the applicable regulations promulgated under the Federal Food, Drug, and Cosmetic Act.

(Signature and post-office address of manufacturer)

(2) For foreign manufacturers.

(Name of manufacturer and agent) hereby severally guarantee that all coal-tar colors listed herein were manufactured by (name of manufacturer), and are from batches certified in accordance with the applicable regulations promulgated under the Federal Food, Drug, and Cosmetic Act.

(Signature and post-office address of manufacturer)

(Signature and post-office address of agent)

(f) For the purpose of a guaranty or undertaking under section 303 (c) (3) of the act the manufacturer of a shipment or other delivery of a coal-tar color is the person who packaged such color.

(g) A guaranty or undertaking, if signed by two or more persons, shall state that such persons severally guarantee the article to which it applies.

(h) No representation or suggestion that an article is guaranteed under the act shall be made in labeling.

(Sec. 303 (c), 52 Stat. 1043; 21 U. S. C. 333 (c))

§ 1.6 *Presentation of views under section 305 of the act.* (a) Presentation of views under section 305 of the act shall be private and informal. The views presented shall be confined to matters relevant to the contemplated proceeding. Such views may be presented by letter or in person by the person to whom the notice was given, or by his representative. In case such person holds a guaranty or undertaking referred to in section 303 (c) (2) or (3) of the act applicable to the article on which such notice was based, such guaranty or undertaking, or a verified copy thereof, shall be made a part of such presentation of views.

(b) Upon request, seasonably made, by the person to whom a notice appointing a time and place for the presentation of views under section 305 of the act has been given, or by his representative, such time or place, or both such time and place, may be changed if the request states reasonable grounds therefor. Such request shall be addressed to the office of the Food and Drug Administration which issued the notice.

(Sec. 305, 52 Stat. 1045; 21 U. S. C. 335)

FOOD

AUTHORITY: §§ 1.7 to 1.14 issued under sec. 701 (a), 52 Stat. 1055; 21 U. S. C. 371 (a). Statutory provisions interpreted or applied are cited to text in parentheses.

§ 1.7 *Food; labeling; misbranding.* (a) Among representations in the labeling of a food which render such food misbranded is a false or misleading representation with respect to another food or a drug, device, or cosmetic.

(b) The labeling of a food which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such food in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

(Sec. 403 (a), 52 Stat. 1047; 21 U. S. C. 343 (a))

§ 1.8 *Food; labeling; required statements; when exempt.* (a) Where a food is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such food, such as "Manufactured for and Packed by ——," "Distributed by ——," or other similar phrase which expresses the facts.

(b) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(c) If a person manufactures, packs, or distributes a food at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such food was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(d) The requirement that the label shall contain the name and place of business of the manufacturer, packer, or distributor shall not be considered to relieve any food from the requirement that its label shall not be misleading in any particular.

(e) (1) The statement of the quantity of the contents shall reveal the quantity of food in the package, exclusive of wrappers and other material packed with such food.

(2) The statement shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure, which are generally used by consumers to express quantity of such food and which give accurate information as to the quantity thereof. But if no general consumer usage in expressing accurate information as to the quantity of such food exists, the statement shall be in terms of liquid measure if the food is liquid, or in terms of weight if the food is solid, semisolid, viscous, or a mixture of solid and liquid; except that such statement may be in terms of dry measure if the food is a fresh fruit, fresh vegetable, or other dry commodity.

(f) (1) A statement of weight shall be in terms of the avoirdupois pound and ounce. A statement of liquid measure shall be in terms of the United States gallon of 231 cubic inches and quart, pint, and fluid ounce subdivisions thereof, and, except in case of frozen food which is so consumed, shall express the volume at 68° Fahrenheit (20° Centigrade). A statement of dry measure shall be in terms of the United States bushel of 2150.42 cubic inches and peck, dry quart, and dry pint subdivisions thereof; or in terms of the United States standard barrel and its subdivisions of third, half, and three-quarters barrel. However, in the case of an export shipment, the statement may be in terms of a system of weight or measure in common use in the country to which such shipment is exported.

(2) A statement of weight or measure in the terms specified in subparagraph (1) of this paragraph may be supplemented by a statement in terms of the metric system of weight or measure.

(3) Unless an unqualified statement of numerical count gives accurate information as to the quantity of food in the package, it shall be supplemented by such statement of weight, measure, or size of the individual units of the foods as will give such information.

(g) Statements shall contain only such fractions as are generally used in expressing the quantity of the food. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places.

(h) (1) If the quantity of food in the package equals or exceeds the smallest unit of weight or measure which is specified in paragraph (f) of this section, and which is applicable to such food under the provisions of paragraph (e) (2) of this section, the statement shall express the number of the largest of such units contained in the package (for example, the statement on the label of a package which contains one quart of food shall be "1 quart", and not "2 pints" or "32 fluid ounces"), unless the statement is made in accordance with the provisions of subparagraph (2) of this paragraph. Where such number is a whole number and a fraction, there may be substituted for the fraction its equivalent in smaller units, if any smaller is specified in such paragraph (f) (for examples, 1¾ quarts may be expressed as "1 quart 1½ pints" or "1 quart 1 pint 8 fluid ounces"; 1¼ pounds may be expressed as "1 pound 4 ounces"). The stated number of any unit which is smaller than the largest unit (specified in such paragraph (f)) contained in the package shall not equal or exceed the number of such smaller units in the next larger unit so specified (for examples, instead of "1 quart 16 fluid ounces" the statement shall be "1½ quarts" or "1 quart 1 pint"; instead of "24 ounces" the statement shall be "1½ pounds" or "1 pound 8 ounces").

(2) In the case of a food with respect to which there exists an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be made in accordance with such custom if it is informative to consumers.

(i) The statement shall express the minimum quantity, or the average quantity, of the contents of the packages. If the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement shall be considered to express the average quantity.

(j) Where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure caused by ordinary and customary exposure, after the food is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large.

(k) Where the statement does not express the minimum quantity:

(1) Variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure, after the food is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure;

(2) Variations from the stated weight, measure, or numerical count shall be permitted when caused by unavoidable deviations in weighing, measuring, or counting individual packages which occur in good packing practice.

But under subparagraph (2) of this paragraph variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or other delivery of the food is below the quantity stated, and no unreasonable shortage in any package shall be permitted, even though overages in other packages in the same shipment or delivery compensate for such shortage.

(l) The extent of variations from the stated quantity of the contents permissible under paragraphs (j) and (k) of this section in the case of each shipment or other delivery shall be determined by the facts in such case.

(m) A food shall be exempt from compliance with the requirements of clause (2) of section 403 (e) of the act if:

(1) The quantity of the contents, as expressed in terms applicable to such food under the provisions of paragraph (e) (2) of this section, is less than one-half ounce avoirdupois, or less than one-half fluid ounce, or (in case the units of the food can be easily counted without opening the package) less than six units; or

(2) The statement of the quantity of the contents of the package, together with all other words, statements, and information required by or under authority of the act to appear on the label, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of section 403 (f) of the act and regulations promulgated thereunder.

(n) A food shall be exempt while held for sale from the requirements of clause (2) of section 403 (e) of the act (requiring a statement on the label of the quantity of contents) if said food, having been received in bulk containers at a retail establishment, is accurately weighed, measured, or counted either within the view of the purchaser or in compliance with the purchaser's order.

(Sec. 403 (e), 52 Stat. 1047; 21 U. S. C. 343 (e))

§ 1.9 *Food; labeling; prominence of required statements.* (a) A word, statement, or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by section 403 (f) of the act by reason (among other reasons) of:

(1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(5) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or

(6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under section 403 (e) or (i) of the act, shall apply if such insufficiency is caused by:

(1) The use of label space for any word statement, design, or device which is not required by or under authority of the act to appear on the label;

(2) The use of label space to give greater conspicuousness to any word, statement, or other information than is required by section 403 (f) of the act; or

(3) The use of label space for any representation in a foreign language.

(c) (1) All words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language.

(3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear on the labeling in the foreign language.

(Sec. 403 (f), 52 Stat. 1047; 21 U. S. C. 343 (f))

§ 1.10 *Food; labeling; designation of ingredients.* (a) The name of an ingredient (except a spice, flavoring, or coloring which is an ingredient of a food other than one sold as a spice, flavoring, or coloring), required by section 403 (i) (2) of the act to be borne on the label of a food, shall be a specific name and not a collective name. But if an ingredient (which itself contains two or more ingredients) conforms to a definition and standard of identity prescribed by regulations under section 401 of the act, such ingredient may be designated on the label of such food by the name specified in the definition and standard, supplemented, in case such regulations require the naming of optional ingredients present in such ingredient, by a statement showing the optional ingredients which are present in such ingredient.

(b) No ingredient shall be designated on the label as a spice, flavoring, or coloring unless it is a spice, flavoring, or coloring, as the case may be, within the meaning of such term as commonly understood by consumers. The term "coloring" shall not include any bleaching substance.

(c) An ingredient which is both a spice and a coloring, or both a flavoring and a coloring, shall be designated as spice and coloring, or flavoring and coloring, as the case may be, unless such ingredient is designated by its specific name.

(d) A label may be misleading by reason (among other reasons) of:

(1) The order in which the names of ingredients appear thereon, or the relative prominence otherwise given such names; or

(2) Its failure to reveal the proportion of, or other fact with respect to, an ingredient, when such proportion or other fact is material in the light of the representation that such ingredient was used in fabricating the food.

(e) (1) A food shall be exempt from the requirements of clause (2) of section 403 (i) of the act if all words, statements, and other information required by or under authority of the act to appear on the label of such food, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of section 403 (f) of the act and regulations promulgated thereunder. But such exemption shall be on the condition that, if the omission from the label of the statement of the quantity of the contents affords sufficient space to state legibly thereon all the information required by such clause (2), such statement of the quantity of the contents shall be omitted as authorized by § 1.8 (m) (2), and the information required by such clause (2) shall be so stated as prominently as practicable even though the statement is not of such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase.

(2) In the case of an assortment of different items of food, when variations in the items which make up different packages packed from such assortment normally occur in good packing practice, and when such variations result in variations in the ingredients in different packages, such food shall be exempt from compliance with the requirements of clause (2) of section 403 (i) of the act with respect to any ingredient which is not common to all packages. But such exemption shall be on the condition that the label shall bear, in conjunction with the names of such ingredients as are common to all packages, a statement in

terms which are as informative as practicable and which are not misleading, indicating that other ingredients may be present.

(f) A food shall be exempt while held for sale from the requirements of clause (2) of section 403 (i) of the act (requiring a declaration on the label of the common or usual name of each ingredient when the food is fabricated from two or more ingredients) if said food, having been received in bulk containers at a retail establishment, is displayed to the purchaser with either (1) the labeling of the bulk container plainly in view or (2) a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required to be stated on the label pursuant to clause (2) of section 403 (i).

(Sec. 403 (i), 52 Stat. 1048; 21 U. S. C. 343 (i))

§ 1.11 *Special dietary uses.* (a) The term "special dietary uses", as applied to food for man, means particular (as distinguished from general) uses of food, as follows:

(1) Uses for supplying particular dietary needs which exist by reason of a physical, physiological, pathological or other condition, including but not limited to the conditions of disease, convalescence, pregnancy, lactation, allergic hypersensitivity to food, underweight, and overweight;

(2) Uses for supplying particular dietary needs which exist by reason of age, including but not limited to the ages of infancy and childhood;

(3) Uses for supplementing or fortifying the ordinary or usual diet with any vitamin, mineral, or other dietary property. Any such particular use of a food is a special dietary use, regardless of whether such food also purports to be or is represented for general use.

(b) No provision of any regulation under section 403 (j) of the act shall be construed as exempting any food from any other provision of the act or regulations thereunder, including sections 403 (a) and (g) and, when applicable, the provisions of Chapter V of the act.

§ 1.12 *Food; labeling; artificial flavoring or coloring, chemical preservatives.* (a) (1) The term "artificial flavoring" means a flavoring containing any sapid or aromatic constituent, which constituent was manufactured by a process of synthesis or other similar artifice.

(2) The term "artificial coloring" means a coloring containing any dye or pigment, which dye or pigment was manufactured by a process of synthesis or other similar artifice, or a coloring which was manufactured by extracting a natural dye or natural pigment from a plant or other material in which such dye or pigment was naturally produced.

(3) The term "chemical preservative" means any chemical which, when added to food, tends to prevent or retard deterioration thereof; but does not include common salt, sugars, vinegars, spices or oils extracted from spices, or substances added to food by direct exposure thereof to wood smoke.

(b) A food which is subject to the requirements of section 403 (k) of the act shall bear labeling, even though such food is not in package form.

(c) A statement of artificial flavoring, artificial coloring, or chemical preservative shall be placed on the food, or on its container or wrapper, or on any two or all of these, as may be necessary to render such statement likely to be read by the ordinary individual under customary conditions of purchase and use of such food.

(d) A food shall be exempt from compliance with the requirements of section 403 (k) of the act if it is not in package form and the units thereof are so small that a statement of artificial flavoring, artificial coloring, or chemical preservative, as the case may be, cannot be placed on such units with such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase and use.

(e) A food shall be exempt while held for sale from the requirements of section 403 (k) of the act (requiring label statement of any artificial flavoring, artificial coloring, or chemical preservatives) if said food, having been received in bulk containers at a retail establishment, is displayed to the purchaser with either (1) the labeling of the bulk container plainly in view or (2) a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required to be stated on the label pursuant to section 403 (k).

(Sec. 403 (k), 52 Stat. 1048; 21 U. S. C. 343 (k))

§ 1.13 *Food; exemptions from labeling requirements.* (a) (1) An open container is a container of rigid or semirigid construction, which is not closed by lid, wrapper, or otherwise.

(2) An open container of a fresh fruit or fresh vegetable, the quantity of contents of which is not more than one dry quart, shall be exempt from the labeling requirements of paragraphs (e), (g) (2) (with respect to the name of the food specified in the definition and standard), and (i) (1) of section 403 of the act; but such exemption shall be on the condition that if two or more such containers are enclosed in a crate or other shipping package, such crate or package shall bear labeling showing the number of such containers enclosed therein and the quantity of the contents of each.

(b) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of a food which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling requirements of section 403 (c), (e), (g), (h), (i), (j) and (k) of the act if:

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such food is to be processed, labeled, or repacked; or

(2) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post-office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such food in such establishment as will insure, if such specifications are followed, that such food will not be adulterated or misbranded within the meaning of the act upon completion of such processing labeling, or repacking. Such person and such operator, shall each keep a copy of such agreement until all of such shipment or delivery has been removed from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Department who requests them.

(c) An exemption of a shipment or other delivery of a food under paragraph (b) (1) of this section shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment become void ab initio if the food comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed.

(d) An exemption of a shipment or other delivery of a food under paragraph (b) (2) of this section shall become void ab initio with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by such paragraph.

(e) An exemption of a shipment or other delivery of a food under paragraph (b) (2) of this section shall expire:

(1) At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the food comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed; or

(2) Upon refusal by the operator of the establishment where such food is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such paragraph.

(f) The word "processed" shall include the holding of cheese in a suitable warehouse at a temperature of not less than 35° F. for the purpose of aging or curing to bring the cheese into compliance with requirements of an applicable definition and standard of identity. The exemptions provided for in paragraph (b) of this section shall apply to cheese which is, in accordance with the practice of the trade, shipped to a warehouse for aging or curing, on condition that the cheese is identified in the manner set forth in one of the applicable following subparagraphs, and in such case paragraphs (c), (d), and (e) of this section shall also apply:

(1) In the case of varieties of cheeses for which definitions and standards of identity require a period of aging, whether or not they are made from pasteurized milk, each such cheese shall bear on the cheese a legible mark showing the date at which the preliminary

manufacturing process has been completed and at which date curing commences, and to each cheese, on its wrapper or immediate container, shall be affixed a removable tag bearing the statement "Uncured ____________ cheese for completion of curing and proper labeling," the blank being filled in with the applicable name of the variety of cheese. In the case of swiss cheese, the date at which the preliminary manufacturing process had been completed and at which date curing commences is the date on which the shaped curd is removed from immersion in saturated salt solution as provided in the definition and standard of identity for swiss cheese, and such cheese shall bear a removable tag reading, "To be cured and labeled as 'swiss cheese', but if eyes do not form to be labeled as 'swiss cheese for manufacturing.' "

(2) In the case of varieties of cheeses which when made from unpasteurized milk are required to be aged for not less than 60 days, each such cheese shall bear a legible mark on the cheese showing the date at which the preliminary manufacturing process has been completed and at which date curing commences, and to each such cheese or its wrapper or immediate container shall be affixed a removable tag reading, "____________ cheese made from unpasteurized milk. For completion of curing and proper labeling," the blank being filled in with the applicable name of the variety of cheese.

(3) In the case of cheddar cheese, washed curd cheese, colby cheese, granular cheese, and brick cheese made from unpasteurized milk, each such cheese shall bear a legible mark on the cheese showing the date at which the preliminary manufacturing process has been completed and at which date curing commences, and to each such cheese or its wrapper or immediate container shall be affixed a removable tag reading "____________ cheese made from unpasteurized milk. For completion of curing and proper labeling, or for labeling as ______________ cheese for manufacturing," the blank being filled in with the applicable name of the variety of cheese.

(Sec. 405, 52 Stat. 1049; 21 U. S. C. 345)

§ 1.14 *Conformity to definitions and standards of identity.* In the following conditions, among others, a food does not conform to the definition and standard of identity therefor:

(a) If it contains an ingredient for which no provision is made in such definition and standard;

(b) If it fails to contain any one or more ingredients required by such definition and standard;

(c) If the quantity of any ingredient or component fails to conform to the limitation, if any, prescribed therefor by such definition and standard.

DRUGS AND DEVICES

AUTHORITY: §§ 1.100 to 1.115 issued under sec. 701 (a), 52 Stat. 1055; 21 U. S. C. 371 (a). Statutory provisions interpreted or applied are cited to text in parentheses.

§ 1.100 *Drugs; name.* (a) The name by which a drug is designated shall be clearly distinguishing and differentiating from any name recognized in an official compendium unless such drug complies in identity with the identity prescribed in an official compendium under such recognized name.

(b) The term "drug defined in an official compendium" means a drug having the identity prescribed for a drug in an official compendium.

(c) A statement that a drug defined in an official compendium differs in strength, quality, or purity from the standard of strength, quality, or purity set forth for such drug in an official compendium shall show all the respects in which such drug so differs, and the extent of each such difference.

(Sec. 501 (b), 52 Stat. 1049; 21 U. S. C. 351 (b))

§ 1.101 *Drugs and devices; labeling, misbranding.* (a) Among representations in the labeling of a drug or device which render such drug or device misbranded is a false or misleading representation with respect to another drug or device or a food or cosmetic.

(b) The labeling of a drug which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such drug in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

(Sec. 502 (a), 52 Stat. 1050; 21 U. S. C. 352 (a))

§ 1.102 *Drugs and devices; labeling requirements.* (a) If a drug or device is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such drug or device, such as "Manufactured for and Packed by ————," "Distributed by ————," or other similar phrase which expresses the facts.

(b) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(c) Where a person manufactures, packs, or distributes a drug or device at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such drug or device was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(d) The requirement that the label shall contain the name and place of business of the manufacturer, packer, or distributor shall not be considered to relieve any drug or device from the requirement that its label shall not be misleading in any particular.

(e) (1) The statement of the quantity of the contents of a package of a drug shall reveal the quantity of such drug in the package, exclusive of wrappers and other material packed with such drug.

(2) The statement shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure, which are generally used by consumers and users of such drug to express quantity thereof and which give accurate information as to such quantity. But if no general usage in expressing accurate information as to the quantity of such drug exists among consumers and users thereof, the statement of the quantity of a drug which is not in tablet, capsule, ampule, or other unit form shall be in terms of weight if the drug is solid, semisolid, or viscous, or in terms of measure if the drug is liquid; the statement of the quantity of a drug which is in such unit form shall be in terms of the numerical count of such units, supplemented, when necessary to give accurate information as to the quantity of such drug in the package, by such statement (in such terms, manner, and form as are not misleading) of the weight or measure of such units, or of the quantity of each active ingredient in each such unit, as will give such information.

(3) The statement of the quantity of a device shall be expressed in terms of numerical count.

(f) A statement of weight shall be in terms of the avoirdupois pound, ounce, and grain, or of the kilogram, gram, and milligram. A statement of liquid measure shall be in terms of the United States gallon of 231 cubic inches and quart, pint, fluid ounce, and fluid dram subdivisions thereof, or of the liter, milliliter, or cubic centimeter, and shall express the volume at 68° Fahrenheit (20° Centigrade).

(g) Statements of the quantity of a drug shall contain only such fractions as are generally used in expressing the quantity of such drug. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than three places, except in the case of a statement of the quantity of an active ingredient in a unit of a drug.

(h) (1) Unless made in accordance with the provisions of subparagraph (2) of this paragraph, a statement of the quantity of a drug, in the terms of weight or measure applicable to such drug under the provisions of paragraph (e) (2) of this section, shall express the number of the largest unit specified in paragraph (f) of this section which is contained in the package (for example, the statement on the label of a package which contains one pint of a drug shall be "1 pint," and not "16 fluid ounces"). Where such number is a whole number and a fraction, there may be substituted for the fraction its equivalent in smaller units, if any smaller is specified in such paragraph (f) (for example, 1¼ pounds may be expressed as "1 pound 4 ounces"). The stated number of any unit which is smaller than the largest unit (specified in such paragraph (f)) contained in the package shall not equal or exceed the number of such smaller units in the next larger unit so specified (for example, instead of "1 quart 16 fluid ounces" the statement shall be "1½ quarts" or "1 quart 1 pint").

(2) In the case of a drug with respect to which there exists an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in

the package, or as units smaller than the largest unit contained therein, the statement may be made in accordance with such custom if it is informative to consumers.

(i) The statement of the quantity of a drug or device shall express the minimum quantity, or the average quantity, of the contents of the packages. If the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement, except in the case of ampules, shall be considered to express the average quantity. The statement of the quantity of a drug in ampules shall be considered to express the minimum quantity.

(j) Where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure of a drug caused by ordinary and customary exposure, after such drug is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large. In the case of a liquid drug in ampules the variation above the stated measure shall comply with the excess volume prescribed by The National Formulary for filling of ampules.

(k) Where the statement does not express the minimum quantity:

(1) Variations from the stated weight or measure of a drug shall be permitted when caused by ordinary and customary exposure, after such drug is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure;

(2) Variations from the stated weight, measure, or numerical count of a drug or device shall be permitted when caused by unavoidable deviations in weighing, measuring, or counting the contents of individual packages which occur in good packing practice.

But under subparagraph (2) of this paragraph variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or other delivery of the drug or device is below the quantity stated and no unreasonable shortage in any package shall be permitted, even though overages in other packages in the same shipment or delivery compensate for such shortage.

(l) The extent of variations from the stated quantity of the contents permissible under paragraphs (j) and (k) of this section in the case of each shipment or other delivery shall be determined by the facts in such case.

(m) A drug or device shall be exempt from compliance with the requirements of clause (2) of section 502 (b) of the act if:

(1) The statement of the quantity of the contents, as expressed in terms applicable to such drug or device under the provisions of paragraph (e) (2) of this section, together with all other words, statements, and information required by or under authority of the act to appear on the label of such drug or device, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of section 502 (c) of the act and regulations promulgated thereunder, or

(2) The quantity of the contents of the package, as expressed in terms of numerical count in compliance with paragraph (e) (2) or (3) of this section, is less than six units, and such units can be easily counted without opening the package, or

(3) It is an ointment, is labeled "Sample" or "Physician's Sample," or with a substantially similar statement, and the contents of the package do not weigh more than 8 grams.

(Sec. 502 (b), 52 Stat. 1050; 21 U. S. C. 352 (b))

§ 1.103 *Drugs and devices; forms of making required statements.* (a) A word, statement, or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by section 502 (c) of the act by reason (among other reasons) of:

(1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(5) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device; or

(6) Smallness or style of type in which such word, statement, or information appears, insufficient background contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b) No exemption depending on insufficiency of label space, as prescribed in regulations promulgated under section 502 (b) or (e) of the act, shall apply if such insufficiency is caused by:

(1) The use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(2) The use of label space to give greater conspicuousness to any word, statement, or other information than is required by section 502 (c) of the act; or

(3) The use of label space for any representation in a foreign language.

(c) (1) All words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language.

(3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear on the labeling in the foreign language.

(Sec. 502 (c), 52 Stat. 1050; 21 U. S. C. 352 (c))

§ 1.104 *Habit-forming drugs; label requirements.* (a) (1) The name of a substance or derivative required to be borne on the label of a drug by section 502 (d) of the act shall be the common or usual name of such substance or derivative, unless it is designated solely by a name recognized in an official compendium and such designation complies with the provisions of section 502 (c).

(2) A statement on the label of a drug of the name of a constituent, which constituent is a chemical derivative of a substance named in section 502 (d) of the act, shall show the substance from which such constituent is derived and that such constituent is a derivative thereof.

(b) If the drug is in tablet, capsule, ampule, or other unit form, the statement of the quantity or proportion of such substance or derivative contained therein shall express the weight or measure of such substance or derivative in each such unit. If the drug is not in such unit form the statement shall express the weight or measure of such substance or derivative in a specified unit of weight or measure of the drug. Such statement shall be in terms which are informative to the ordinary consumer and user of the drug.

(c) The names and quantities or proportions of all such substances and derivatives, and the statement "Warning—May be habit forming," shall immediately follow (without intervening written, printed, or graphic matter) the name by which such drug is titled in the part or panel of the label thereof which is presented or displayed under customary conditions of purchase.

(d) A drug shall not be considered to be misbranded by reason of failure of its label to bear the statement "Warning—May be habit forming":

(1) If such drug is not suitable for internal use, and is distributed and sold exclusively for such external use as involves no possibility of habit formation; or

(2) If the only substance or derivative subject to section 502 (d) of the act contained in such drug is chlorobutanol, which is present solely as a preservative and in a quantity not more than 0.5 percent by weight, and such drug is for parenteral use only; or

(3) If the only substance or derivative subject to section 502 (d) of the act contained in such drug is chlorobutanol which is present as an analgesic or as an analgesic and a preservative in a quantity not more than 3.0 percent, and such drug contains one or more other active ingredients and is for parenteral use only.

§ 1.105 *Drugs; statement of ingredients and proportion.* (a) (1) The name of an ingredient, substance, derivative, or preparation required by section 502 (e) (2) of the act to be borne on the label of a drug shall be the name thereof which is listed in such section 502 (e) (2) of the act, or, if not so listed, shall be a specific name and not a collective name. But if an ingredient is an article the name of which is recognized in an official compendium and such article complies with the specifications set forth therefor in such compendium, such ingredient may be designated on the label of such drug by the common or usual name under which such specifications are so set forth.

(2) Where an ingredient contains a substance the quantity or proportion of which is required by section 502 (e) (2) of the act to appear on the label, and such ingredient is not a derivative or preparation of such substance as defined in paragraph (b) (1) of this section, the label shall bear, in conjunction with the name of the ingredient, a statement of the quantity or proportion of such substance in such drug.

(3) An abbreviation or chemical formula shall not be considered to be a common or usual name. The name "acetophenetidin" shall be considered to be the same as the name "acetphenetidin," "aminopyrine" the same as "amidopyrine." The name "alcohol" without qualification, means ethyl alcohol.

(b) (1) A derivative or preparation of a substance named in section 502 (e) (2) of the act is an article which is derived or prepared from such substance by any method, including actual or theoretical chemical action.

(2) A statement on the label of a drug of the name of an ingredient thereof, which ingredient is a derivative or preparation of a substance named in section 502 (e) (2) of the act, shall show the substance from which such ingredient is derived or prepared and that such ingredient is a derivative or preparation thereof.

(c) (1) If the drug is in tablet, capsule, ampul, or other unit form, the statement of the quantity or proportion of a substance, derivative, or preparation contained therein shall express the weight or measure of such substance, derivative, or preparation in each such unit. If the drug is not in such unit form the statement shall express the weight or measure of such substance, derivative, or preparation in a specified unit of weight or measure of the drug, or the percentage of such substance, derivative, or preparation in such drug. Such statement shall be in terms which are informative to the ordinary consumer and user of the drug.

(2) A statement of the percentage of alcohol shall express the percentage of absolute alcohol at 60° Fahrenheit (15.56° Centigrade). A statement of the percentage of a substance, derivative, or preparation other than alcohol shall express the percentage by weight; except that, if both the substance, derivative, or preparation and the drug containing it are liquid, the statement may express the percentage by volume at 68° Fahrenheit (20° Centigrade), but in such case the statement shall be so qualified as to show definitely that the percentage is expressed by volume.

(d) In case a statement of the quantity or proportion of a derivative or preparation in a drug is not as informative, to consumers or users of such drug, of the activity or consequences of use thereof as a statement of the quantity or proportion of the substance from which such derivative or preparation is derived or prepared, the quantity or proportion of such substance shall also be stated on the label of such drug.

(e) A label of a drug may be misleading by reason (among other reasons) of:

(1) The order in which the names of ingredients, substances, derivatives, or preparations appear thereon, or the relative prominence otherwise given such names; or

(2) Its failure to reveal the proportion of, or other fact with respect to, an ingredient, substance, derivative, or preparation, when such proportion or other fact is material in the light of the representation that such ingredient, substance, derivative, or preparation is a constituent of such drug.

(f) (1) A drug shall be exempt from the requirements of clause (2) of section 502 (e) of the act if all words, statements, and other information required by or under authority of the act to appear on the label of such drug, cannot, because of insufficient label space, be so placed on the label as to comply with the requirements of section 502 (c) of the act and regulations promulgated thereunder. But such exemption shall be on the condition that, if the omission from the label of the statement of the quantity of the contents affords sufficient space to state legibly thereon all the information required by such clause (2), such statement of the quantity of the contents shall be omitted as authorized by § 1.102 (m) (1), and the information required by such clause (2) shall be so stated as prominently as practicable even though the statement is not of such conspicuousness as to render it likely to be read by the ordinary individual under customary conditions of purchase.

(2) A drug shall be exempt from the requirements of clause (2) of section 502 (e) of the act with respect to the alkaloids atropine, hyoscine or hyoscyamine contained in such drug, if such alkaloid is contained therein as a constituent of belladonna, hyoscyamus, scopola, stramonium, or other plant material, or any preparation thereof, which was used as an ingredient of such drug, and no practical and accurate method of analysis exists for the quantitative determination of each such alkaloid in such ingredient. But such exemption shall be on the condition that the label of such drug shall state the quantity or proportion of total alkaloids contained therein as constituents of such ingredient.

(Sec. 502 (e), 52 Stat. 1050; 21 U. S. C. 352 (e))

§ 1.106 *Drugs and devices; directions for use*—(a) *Adequate directions for use.* "Adequate directions for use" means directions under which the layman can use a drug or device safely and for the purposes for which it is intended. Directions for use may be inadequate because (among other reasons) of omission, in whole or in part, or incorrect specification of:

(1) Statements of all conditions, purposes, or uses for which such drug or device is intended, including conditions, purposes, or uses for which it is prescribed, recommended, or suggested in its oral, written, printed, or graphic advertising, and conditions, purposes, or uses for which the drug or device is commonly used; except that such statements shall not refer to conditions, uses, or purposes for which the drug or device can be safely used only under the supervision of a practitioner licensed by law and for which it is advertised solely to such practitioner.

(2) Quantity of dose (including usual quantities for each of the uses for which it is intended and usual quantities for persons of different ages and different physical conditions).

(3) Frequency of administration or application.

(4) Duration of administration or application.

(5) Time of administration or application (in relation to time of meals, time of onset of symptoms, or other time factors).

(6) Route or method of administration or application.

(7) Preparation for use (shaking, dilution, adjustment of temperature, or other manipulation or process).

(b) *Exemption for prescription drugs.* A drug subject to the requirements of section 503 (b) (1) of the act shall be exempt from section 502 (f) (1) if all the following conditions are met:

(1) The drug is:

(i) In the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale distribution of prescription drugs; or

(ii) In the possession of a retail, hospital, or clinic pharmacy, or a public health agency, regularly and lawfully engaged in dispensing prescription drugs;

and is to be dispensed in accordance with section 503 (b).

(2) The label of the drug bears:

(i) The statement "Caution: Federal law prohibits dispensing without prescription"; and

(ii) The recommended or usual dosage; and

(iii) The route of administration, if it is not for oral use; and

(iv) If it is fabricated from two or more ingredients and is not designated conspicuously by a name recognized in an official compendium, the quantity or proportion of each active ingredient, and if it is not for oral use the names of all other ingredients.

Provided, however, That the information referred to in subdivisions (ii), (iii), and (iv) of this subparagraph may be contained in the labeling on or within the package from which it is to be dispensed, and, in the case of ampuls too small or otherwise unable to accommodate a label but which are packaged in a container from which they are withdrawn for dispensing or use, the information referred to in subdivision (i) of this subparagraph may be placed on the outside container only.

(3) The labeling of the drug (which may include brochures readily available to licensed practitioners) bears information as to the use of the drug by practitioners licensed by law to administer it: *Provided, however*, That such information may be omitted from the labeling if it is contained in scientific literature widely disseminated among practitioners licensed by law to administer the drug.

(c) *Exemption for veterinary drugs.* A drug intended solely for veterinary use which, because of toxicity or other potentiality for harmful effect, or the method of its use, is not safe for animal use except under the supervision of a licensed veterinarian, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502 (f) (1) of the act if all the following conditions are met:

(1) The drug is in the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of veterinary drugs and is to be sold only to or on the prescription or other order of a licensed veterinarian for use in the course of his professional practice.

(2) The label of a drug bears:

(i) The statement "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian"; and

(ii) The recommended or usual dosage; and

(iii) The route of administration, if it is not for oral use; and

(iv) The quantity or proportion of each active ingredient if it is fabricated from two or more ingredients and is not designated conspicuously by a name recognized in an official compendium.

Provided, however, That the information referred to in subdivisions (ii), (iii), and (iv) of this subparagraph may be contained in the labeling on or within the package from which it is to be dispensed.

(3) The labeling of the drug (which may include brochures readily available to licensed veterinarians) bears information as to use of the drug by licensed veterinarians: *Provided, however*, That such information may be omitted from the labeling if it is contained in scientific literature widely disseminated among veterinarians licensed by law to administer such drug.

(d) *Exemption for prescription devices.* A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which "adequate directions for use" cannot be prepared, shall be exempt from section 502 (f) (1) of the act if all the following conditions are met:

(1) The device is in the possession of a person (or his agents or employees) regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device and is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

(2) The label of the device (other than surgical instruments) bears:

(i) The statement "Caution: Federal law restricts this device to sale by or on the order of a ___________," the blank to be filled with the word "physician," "dentist," "veterinarian," or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device; and

(ii) The method of its application or use.

(3) The labeling of the device (which may include brochures readily available to licensed practitioners) bears information as to the use of the device by practitioners licensed by law to use it or direct its use: *Provided, however*, That such information may be omitted from the labeling if it is contained in scientific literature widely disseminated among practitioners licensed by law to use or order the use of such device.

(e) *Exemptions for drugs and devices shipped directly to licensed practitioners, hospitals, clinics, or public-health agencies for professional use.* Except as provided in paragraph (g) of this section, a drug or device shipped directly to or in the possession of a practitioner licensed by law to administer the drug or to use or direct the use of the device, or shipped directly to or in the possession of a hospital, clinic, or public-health agency, for use in the course of the professional practice of such a licensed practitioner, shall be exempt from section 502 (f) (1) of the act if it meets the conditions of paragraphs (b) (2) and (3), (c) (2) and (3), or (d) (2) and (3) of this section.

(f) *Retail exemption for veterinary drugs and prescription devices.* A drug or device subject to paragraph (c) or (d) of this section shall be exempt at the time of delivery to the ultimate purchaser or user from section 502 (f) (1) of the act if it is delivered by a licensed practitioner in the course of his professional practice or upon a prescription or other order lawfully issued in the course of his professional practice, with labeling bearing the name and address of such licensed practitioner and the directions for use and cautionary statements, if any, contained in such order.

(g) *Exemption for new drugs.* A new drug shall be exempt from section 502 (f) (1) of the act:

(1) To the extent to which such exemption is claimed in an effective application with respect to such drug under section 505 of the act; or

(2) If no application under section 505 of the act is effective with respect to such drug but it complies with section 505 (i) and regulations thereunder.

No exemption shall apply to any other drug which would be a new drug if its labeling bore representations for its intended uses.

(h) *Exemption for drugs or devices when directions are commonly known.* A drug or device shall be exempt from section 502 (f) (1) of the act insofar as adequate directions for common uses thereof are known to the ordinary individual.

(i) *Exemptions for inactive ingredients.* A harmless drug that is ordinarily used as an inactive ingredient, such as a coloring, emulsifier, excipient, flavoring, lubricant, preservative, or solvent, in the preparation of other drugs shall be exempt from section 502 (f) (1) of the act. This exemption shall not apply to any substance intended for a use which results in the preparation of a new drug, unless an effective new-drug application provides for such use.

(j) *Exemption for diagnostic reagents.* A drug intended solely for use in the professional diagnosis of disease and which is generally recognized by qualified experts as useful for that purpose shall be exempt from section 502 (f) (1) of the act if its label bears the statement "Diagnostic reagent—For professional use only."

(k) *Exemption for prescription chemicals and other prescription components.* A drug prepared, packaged, and primarily sold as a prescription chemical or other component for use by registered pharmacists in compounding prescriptions or for dispensing in dosage unit form upon prescriptions shall be exempt from section 502 (f) (1) of the act if all the following conditions are met:

(1) The drug is an official liquid acid or official liquid alkali, or is not a liquid solution, emulsion, suspension, tablet, capsule, or other dosage unit form; and

(2) The label of the drug bears:

(i) The statement "For prescription compounding"; and

(ii) If in substantially all dosage forms in which it may be dispensed it is subject to section 503 (b) (1) of the act, the statement "Caution: Federal law prohibits dispensing without prescription"; or

(iii) If it is not subject to section 503 (b) (1) of the act and is by custom among retail pharmacists sold in or from the interstate package for use by consumers, "adequate directions for use" in the conditions for which it is so sold.

Provided, however, That the information referred to in subdivision (iii) of this subparagraph may be contained in the labeling on or within the package from which it is to be dispensed.

(3) This exemption shall not apply to any substance intended for use in compounding which results in a new drug, unless an effective new-drug application covers such use of the drug in compounding prescriptions.

(l) *Exemption for processing, repacking, or manufacture.* A drug in a bulk package (except tablets, capsules, or other dosage unit forms) or a device intended for processing, repacking, or use in the manufacture of another drug or device shall be exempt from section 502 (f) (1) of the act if its label bears the statement "Caution: For manufacturing, processing, or repacking"; and, if in substantially all dosage forms in which it may be dispensed it is subject to section 503 (b) (1), the statement "Caution: Federal law prohibits dispensing without prescription." This exemption and the exemption under paragraph (k) of this section may be claimed for the same article. But the exemption shall not apply to a substance intended for a use in manufacture, processing, or repacking which causes the finished article to be a new drug, unless:

(1) An effective new-drug application held by the person preparing the dosage form or drug for dispensing covers the production and delivery to him of such substance; or

(2) If no application is effective with respect to such new drug, the label statement "Caution: For manufacturing, processing, or repacking" is immediately supplemented by the words "in the preparation of a new drug limited by Federal law to investigational use," and the delivery is made for use only in the manufacture of such new drug limited to investigational use as provided in § 1.114.

(m) *Exemption for drugs and devices for use in teaching, research, and analysis.* A drug or device subject to paragraph (b), (c), or (d) of this section shall be exempt from section 502 (f) (1) of the act if shipped or sold to, or in the possession of, persons regularly and lawfully engaged in instruction in pharmacy, chemistry, or medicine not involving clinical use, or engaged in research not involving clinical use, or in chemical analysis, or physical testing, and is to be used only for such instruction, research, analysis, or testing.

(n) *Expiration of exemptions.* (1) If a shipment or delivery, or any part thereof, of a drug or device which is exempt under the regulations in this section is made to a person in whose possession the article is not exempt, or is made for any purpose other than those specified, such exemption shall expire, with respect to such shipment or delivery or part thereof, at the beginning of that shipment or delivery. The causing of an exemption to expire shall be considered an act which results in such drug or device being misbranded unless it is disposed of under circumstances in which it ceases to be a drug or device.

(2) The exemptions conferred by paragraphs (i), (j), (k), (l), and (m) of this section shall continue until the drugs or devices are used for the purposes for which they are exempted, or until they are relabeled to comply with section 502 (f) (1) of the act. If, however, the drug is converted, compounded, or manufactured into a dosage form limited to prescription dispensing, no exemption shall thereafter apply to the article unless the dosage form is labeled as required by section 503 (b) and paragraph (b), (c), or (d) of this section.

(o) *Intended uses.* The words "intended uses" or words of similar import in paragraphs (a), (g), (i), (j), (k), and (l) of this section refer to the objective intent of the persons legally responsible for the labeling of drugs and devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the drug, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug or device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put.

§ 1.107 *Drugs and devices; exemptions.* (a) Except as provided by paragraphs (b) and (c) of this section, a shipment or other delivery of a drug or device which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling and packaging requirements of sections 501 (b) and 502 (b), (d), (e), (f), and (g) of the act if:

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such drug or device is to be processed, labeled, or repacked; or

(2) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post-office addresses of such person and such operator, and containing such specifications for the processing, labeling, or repacking, as the case may be, of such drug or device in such establishment as will insure, if such specifications are followed, that such drug or device will not be adulterated or misbranded within the meaning of the act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until all such shipment or delivery has been removed from such establishment, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Agency who requests them.

(b) An exemption of a shipment or other delivery of a drug or device under paragraph (a) (1) of this section shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void ab initio if the drug or device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed.

(c) An exemption of a shipment or other delivery of a drug or device under paragraph (a) (2) of this section shall become void ab initio with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by such subparagraph.

(d) An exemption of a shipment or other delivery of a drug or device under paragraph (a) (2) of this section shall expire:

(1) At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the drug or device comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed; or

(2) Upon refusal by the operator of the establishment where such drug or device is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such clause.

(e) Except as provided in paragraphs (g) and (h) of this section, a shipment or other delivery of a drug which is subject to section 507 of the act and which is, in accordance with the practice of the trade, to be processed or repacked in a substantial quantity at an establishment other than that where originally processed or packed shall be exempt from compliance with the labeling requirements of section 502 (f) of the act during the time such drug is also exempt from the requirements of section 502 (l) of the act under the provisions of § 146.20 or 146.21 of this chapter.

(f) Except as provided by paragraphs (g) and (h) of this section, a shipment or other delivery of a drug which is subject to section 507 of the act and which is, in accordance with the practice of the trade, to be labeled in substantial quantity at an establishment other than that where originally processed or packed shall be exempt from compliance with the labeling requirements of section 502 (b), (e) and (f) of the act during the time such drug is also exempt from the requirements of section 502 (l) of the act under § 146.18 of this chapter, if the words, statements, and other information required by section 502 (b) and (e) of the act appear on each shipping container of such drug.

(g) In case the person who introduced such shipment or other delivery into interstate commerce is the operator of the establishment where such drug is to be processed, labeled, or repacked, an exemption of such shipment or delivery under paragraph (e) or (f) of this section shall become void ab initio at the beginning of the act of removing such shipment or delivery or any part thereof from such establishment if the drug comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed.

(h) In case the person who introduced such shipment or delivery into interstate commerce is not the operator of the establishment where such drug is to be processed, labeled, or repacked, an exemption of a shipment or other delivery of such drug under paragraph (e) or (f) of this section shall expire at the beginning of the act of removing such shipment or delivery or any part thereof from such establishment if the drug comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed.

(Sec. 503 (a), 52 Stat. 1051; 21 U. S. C. 353 (a))

§ 1.108 *Exemption from prescription requirements*—(a) *Exemption for certain habit-forming drugs.* The prescription-dispensing requirements of section 503 (b) (1) (A) of the act are not necessary for the protection of the public health with respect to the following drugs subject to section 502 (d):

(1) Exempt narcotic preparations described in 26 CFR 151.2 and sold as required by 26 CFR 151.180 through 151.185a.

(2) Drugs containing chlorobutanol, intended for external use only.

(3) Epinephrine solution, 1 percent, preserved with chlorobutanol and intended for use solely as a spray.

(4) Drugs containing one or more of the derivatives of barbituric acid and in addition a sufficient quantity or proportion of another drug or drugs to prevent the ingestion of a sufficient amount of barbiturate derivative to cause a hypnotic or somnifacient effect.

(b) *Duration of prescription requirement.* Any drug limited to prescription use under section 503 (b) (1) (C) of the act remains so limited until it is exempted as provided in paragraph (c) of this section.

(c) *Prescription exemption procedure for drugs limited by a new-drug application.* The exemption of a drug from the prescription-dispensing requirements of section 503 (b) (1) (C) of the act may be initiated by the Commissioner or by any interested person. Any interested person may file a petition seeking such exemption, stating reasonable grounds therefor, which petition may be in the form of a supplement to an effective new-drug application. Upon receipt of such a petition, or on his own initiative at any time, the Commissioner will publish a notice of proposed rule making and invite written comments. After consideration of all available data, including any comments submitted, the Commissioner may issue a regulation granting or refusing the exemption, effective on a date specified therein. Whenever the Commissioner concludes, either at the time of publication of the notice of proposed rule making or after considering the written comments submitted, that granting or refusing the exemption requires a more thorough development of the facts than is possible in a written presentation, he may call a public hearing for that purpose. The notice of such hearing shall specify the questions to be considered. As soon as practicable after completion of the hearing, the final regulation granting or refusing the exemption shall be issued, effective on a date specified therein. If the Commissioner for good cause finds (and incorporates the finding and a brief statement of the reasons therefor in a regulation) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, he may issue the final regulation forthwith.

(d) *New-drug status of drugs exempted from the prescription requirement.* A drug exempted from the prescription requirement under the provisions of paragraph (c) of this section continues to be a "new drug" within the meaning of section 201 (p) of the act until it has been used to a material extent or for a material time and has become generally recognized as safe when used in accordance with the directions for use contained in its labeling.

(e) *Prescription legend not allowed on exempted drugs.* The use of the prescription caution statement quoted in section 503 (b) (4) of the act, in the labeling of a drug exempted under the provisions of this section, constitutes misbranding. Any other statement or suggestion in the labeling of a drug exempted under this section, that such drug is limited to prescription use, may constitute misbranding.

(Sec. 503, 52 Stat. 1051, as amended; 21 U. S. C. 353)

NOTE: Paragraph (f) (1) and (2) of § 1.108 has been transferred to Part 130, as § 130.1 (a).

§ 1.109 *New drugs; definition.* Newness of a drug may arise by reason (among other reasons) of:

(a) The newness for drug use of any substance which composes such drug, in whole or in part, whether it be an active substance or a menstruum, excipient, carrier, coating, or other component;

(b) The newness for drug use of a combination of two or more substances, none of which is a new drug;

(c) The newness for drug use of the proportion of a substance in a combination, even though such combination containing such substance in other proportion is not a new drug;

(d) The newness of use of such drug in diagnosing, curing, mitigating, treating, or preventing a disease, or to affect a structure or function of the body even though such drug is not a new drug when used in another disease or to affect another structure or function of the body; or

(e) The newness of a dosage, or method or duration of administration or application, or other condition of use prescribed, recommended, or suggested in the labeling of such drug, even though such drug when used in other dosage, or other method or duration of administration or application, or different condition, is not a new drug.

(Sec. 201 (p), 52 Stat. 1041; 21 U. S. C. 321 (p))

§ 1.109a *New drugs; exemption from section 505 of the act.* A new drug shall not be deemed to be subject to section 505 of the act if it is a drug which is licensed under the Public Health Service Act of July 1, 1944 (58 Stat. 682; 42 U. S. C. 201 et seq.), or under the animal virus-serum-toxin law of March 4, 1913 (37 Stat. 832; 21 U. S. C. 151 et seq.)

§ 1.110 *New drugs; applications.* (a) Each application submitted for filing with the Secretary shall be in duplicate. If any part of the application is in a foreign language, an accurate and complete English translation shall be appended to such part.

(b) An application shall not be accepted for filing if only one copy is submitted or if it is incomplete on its face in that:

(1) It does not contain all the matter required by clauses (1), (2), (3), (4), and (6) of section 505 (b) of the act;

(2) It does not state the conditions under which the drug is to be used; or

(3) The specimens of labeling proposed for use upon or within the retail package do not expressly or by reference to a brochure or other printed matter prescribe, recommend, or suggest the use of such drug under such conditions.

The Food and Drug Administration shall notify the applicant of such nonacceptance and the reason therefor and, in case of incompleteness as to matter required by any clause of section 505 (b), shall specify such clause. Otherwise the date on which an application is received by the Department shall be considered to be the date on which such application is filed, and the Food and Drug Administration shall notify the applicant of such date. If the applicant withdraws his application, such application shall be considered as not having been filed.

(c) The applicant may file an amendment to an application which has been filed and is pending before the Secretary, but in such case the unamended application shall be considered as having been withdrawn and the amended application shall be considered as having been filed on the date on which the amendment is received by the Department. The Food and Drug Administration shall notify the applicant of such date.

(d) After an application has become effective with respect to a drug the applicant may file a supplemental application with respect thereto setting forth any proposed change in the conditions under which such drug is to be used, in the labeling thereof, in any circumstance relating to its production, or in any other information contained in the effective application. Such supplemental application may omit statements made in the effective application concerning which no change is proposed.

§ 1.111 *Notification of applicant.* If the Secretary determines, before the date prescribed by section 505 (c) of the act for an application to become effective, that he has no cause to issue an order under section 505 (d) of the act refusing to permit such application to become effective, the Food and Drug Administration shall so notify the applicant in writing and such application shall become effective on the date of the notification.

(Sec. 505 (c), 52 Stat. 1052; 21 U. S. C. 355 (c))

§ 1.112 *Insufficient information in application.* The information contained in an application may be insufficient for the Secretary to determine whether a drug is safe for use if it fails to include (among other things) a statement showing whether the drug is to be exempt under any provision of § 1.106, as amended, promulgated pursuant to section 502 (f) of the act, from the requirement that its labeling bear adequate directions for use. If the drug is to be so exempt, the information may also be insufficient if:

(a) The specimen label of the drug fails to incorporate by reference a specifically identified brochure or other printed matter containing information adequate for the use of such drug by physicians, dentists, or veterinarians, as the case may be;

(b) Such label fails to state that the drug is to be used as shown in such brochure or printed matter and that such brochure or printed matter will be sent to physicians, dentists, or veterinarians, as the case may be, on request;

(c) The application fails to contain copies of such brochure or printed matter; or

(d) The application fails to show that such brochure or printed matter is readily available to physicians, dentists, or veterinarians, as the case may be, or if not that it is to be made so when the application becomes effective.

§ 1.113 *Untrue statements in application.* Among the reasons why an application may contain an untrue statement of a material fact are changes in:

(a) Conditions of use prescribed, recommended, or suggested by the applicant for the drug from the conditions of such use stated in the application;

(b) Articles used as components of the drug from those listed in the application;

(c) Composition of the drug from that stated in the application;

(d) Methods used in, or the facilities or controls used for, the manufacture, processing, or packing of the drug from such methods, facilities, and controls described in the application; and

(e) Labeling from the specimens contained in the application.

§ 1.114 *New drugs; exemptions from section 505 (a).* (a) Except as provided by paragraph (b) of this section a shipment or other delivery of a new drug shall be exempt from the operation of section 505 (a) of the act if all the following conditions are complied with:

(1) The label of such drugs bears the statement "Caution: New drug—Limited by Federal law to investigational use."

(2) Such shipment or delivery is made only to, and solely for investigational use by or under the direction of, an expert qualified by scientific training and experience to investigate the safety of such drug.

(3) The person who introduced such shipment or delivery into interstate commerce obtains, prior to the introduction, a statement signed by such expert showing that he has adequate facilities for the investigation to be conducted by him, and that such drug will be used solely by him or under his direction for the investigation, unless and until an application becomes effective with respect to such drug under section 505 of the act. This subparagraph shall not apply when such shipment or delivery is made to an agency of the Government of the United States (including the National Research Council), or of any State or municipality, whose official functions involve investigations of new drugs by such experts.

(4) Such person keeps the statement referred to in subparagraph (3) of this paragraph, and complete records showing the date, quantity, and batch or code mark (if any), of each such shipment and delivery.

(5) Such person makes all records and statements referred to in subparagraphs (3) and (4) of this paragraph available for inspection upon the request of any officer or employee of the Department at any reasonable hour until 3 years after the introduction of such shipment or delivery into interstate commerce.

(b) A shipment or other delivery of a new drug which is being imported or offered for import into the United States shall be exempt from the operation of section 505 (a) of the act if all of the following conditions are complied with:

(1) The label of such drug bears the statement "Caution: New drug—Limited by United States law to investigational use."

(2) The importer of all such shipments or deliveries is an agent of the foreign exporter, residing in the United States, or the operator of an establishment in the United States which has facilities for regularly investigating the safety of such drugs, which facilities are manned by experts qualified by scientific training and experience to conduct such investigation.

(3) Such operator uses such drug solely for such investigation in such establishment, or such operator or agent otherwise disposes of such drug only to, and solely for investigational use by or under the direction of, such an expert other than one in such establishment.

(4) Such importer, prior to disposing of any of such drug to such an expert, obtains a statement signed by such expert showing that he has adequate facilities for the investigation to be conducted by him, and that such drug will be used solely by him or under his direction for the investigation, unless and until an application becomes effective with respect to such drug under section 505 of the act. This subparagraph shall not apply to any shipment or delivery or part thereof disposed of by such importer to an agency of the Government of the United States (including the National Research Council) or of any State or municipality whose official functions involve investigations of new drugs by such experts.

(5) Such importer keeps the statement referred to in subparagraph (4) of this paragraph and complete records showing the date, quantity, and batch or code marks (if any), of each such shipment and delivery and the disposition thereof.

(6) Such importer makes all statements and records referred to in subparagraphs (4) and (5) of this paragraph available for inspection upon the request of any officer or employee of the Department at any reasonable hour until 3 years after disposition by such importer of the lot of such drug to which such statement and records relate.

(c) An exemption under paragraph (a) or (b) of this section shall become void ab initio if any record or statement required by such paragraph to be kept and made available for inspection is not kept or made available as so required.

(d) An exemption under paragraph (a) or (b) of this section shall expire with respect to any exempted shipment or delivery or part thereof which has been supplied to an expert who has signed the statement referred to in paragraph (a) (3) or (b) (4) of this section and which is used otherwise than in accordance with such signed statement.

(e) An exemption under paragraph (b) of this section shall become void ab initio if the exempted shipment or delivery or any part thereof is disposed of otherwise than as provided by subparagraph (3) of such paragraph.

(f) No exemption under paragraph (b) of this section shall apply to any shipment or delivery to such importer if such importer, within 3 years prior to the offering of such shipment or delivery for import, has caused an exemption to become void as provided by paragraph (c) or (e) of this section.

(Sec. 505 (i), 52 Stat. 1052; 21 U. S. C. 355 (i))

§ 1.115 *Definition of term "insulin."* For the purposes of sections 502 (k) and 506 of the act, the term "insulin" as used therein means the active principle of pancreas which affects the metabolism of carbohydrate in the animal body and which is of value in the treatment of diabetes mellitus.

COSMETICS

AUTHORITY: §§ 1.200 to 1.204 issued under sec. 701 (a), 52 Stat. 1055; 21 U. S. C. 371 (a). Statutory provisions interpreted or applied are cited to text in parentheses.

§ 1.200 *Cosmetic; coal-tar hair dye defined.* The term "coal-tar hair dye" includes all articles containing any coal-tar color or intermediate which color or intermediate alters the color of the hair when such articles are applied to the hair under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual.

(Sec. 601 (a), 52 Stat. 1054; 21 U. S. C. 361 (a))

§ 1.201 *Cosmetic; labeling; misbranding.* (a) Among representations in labeling of a cosmetic which render such cosmetic misbranded is a false or misleading representation with respect to another cosmetic or a food, drug, or device.

(b) The labeling of a cosmetic which contains two or more ingredients may be misleading by reason (among other reasons) of the designation of such cosmetic in such labeling by a name which includes or suggests the name of one or more but not all such ingredients, even though the names of all such ingredients are stated elsewhere in the labeling.

(Sec. 602 (a), 52 Stat. 1054; 21 U. S. C. 362 (a))

§ 1.202 *Cosmetic; labeling; required statements; exemptions.* (a) If a cosmetic is not manufactured by the person whose name appears on the label, the name shall be qualified by a phrase which reveals the connection such person has with such cosmetic such as "Manufactured for and Packed by ———," "Distributed by ———," or other similar phrase which expresses the facts.

(b) The statement of the place of business shall include the street address, if any, of such place, unless such street address is shown in a current city directory or telephone directory.

(c) Where a person manufactures, packs, or distributes a cosmetic at a place other than his principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such cosmetic was manufactured or packed or is to be distributed, if such statement is not misleading in any particular.

(d) The requirement that the label shall contain the name and place of business of the manufacturer, packer or distributor shall not be considered to relieve any cosmetic from the requirement that its label shall not be misleading in any particular.

(e) (1) The statement of the quantity of the contents shall reveal the quantity of cosmetic in the package, exclusive of wrappers and other material packed with such cosmetic.

(2) The statement shall be expressed in the terms of weight, measure, numerical count, or a combination of numerical count and weight or measure, which are generally used by consumers to express quantity of such cosmetic and which give accurate information as to the quantity thereof. But if no general consumer usage in expressing accurate information as to the quantity of such cosmetic exists, the statement shall be in terms of liquid measure if the cosmetic is liquid, or in terms of weight if the cosmetic is solid, semisolid, or viscous, or in such terms of numerical count, or numerical count and weight or measure, as will give accurate information as to the quantity of the cosmetic in the package.

(f) (1) A statement of weight shall be in terms of the avoirdupois pound and ounce. A statement of liquid measure shall be in terms of the United States gallon of 231 cubic inches and quart, pint, and fluid ounce subdivisions thereof, and shall express the volume at 68° Fahrenheit (20° Centigrade). However, in the case of an export shipment, the statement may be in terms of a system of weight or measure in common use in the country to which such shipment is exported.

(2) A statement of weight or measure in the terms specified in subparagraph (1) of this paragraph may be supplemented by a statement in terms of the metric system of weight or measure.

(3) Unless an unqualified statement of numerical count gives accurate information as to the quantity of cosmetic in the package, it shall be supplemented by such statement of weight, measure, or size of the individual units of the cosmetic as will give such information.

(g) Statements shall contain only such fractions as are generally used in expressing the quantity of the cosmetic. A common fraction shall be reduced to its lowest terms; a decimal fraction shall not be carried out to more than two places.

(h) (1) If the quantity of cosmetic in the package equals or exceeds the smallest unit of weight or measure which is specified in paragraph (f) of this section, and which is applicable to such cosmetic under the provisions of paragraph (e) (2) of this section, the statement shall express the number of the largest of such units contained in the package (for example, the statement on the label of a package which contains one pint of cosmetic shall be "1 pint" and not "16 fluid ounces"), unless the statement is made in accordance with the provisions of subparagraph (2) of this paragraph. Where such number is a whole number and a fraction, there may be substituted for the fraction its equivalent in smaller units, if any smaller is specified in such paragraph (f) (for examples, 1¾ quarts may be expressed as "1 quart 1½ pints" or "1 quart 1 pint 8 fluid ounces"; 1¼ pounds may be expressed as "1 pound 4 ounces"). The stated number of any unit which is smaller than the largest unit (specified in such paragraph (f)) contained in the package shall not equal or exceed the number of such smaller units in the next larger unit so specified (for examples, instead of "1 quart 16 fluid ounces" the statement shall be "1½ quarts" or "1 quart 1 pint"; instead of "24 ounces" the statement shall be "1½ pounds" or "1 pound 8 ounces").

(2) In the case of a cosmetic with respect to which there exists an established custom of stating the quantity of the contents as a fraction of a unit, which unit is larger than the quantity contained in the package, or as units smaller than the largest unit contained therein, the statement may be made in accordance with such custom if it is informative to consumers.

(i) The statement shall express the minimum quantity, or the average quantity, of the contents of the packages. If the statement is not so qualified as to show definitely that the quantity expressed is the minimum quantity, the statement shall be considered to express the average quantity.

(j) Where the statement expresses the minimum quantity, no variation below the stated minimum shall be permitted except variations below the stated weight or measure caused by ordinary and customary exposure, after the cosmetic is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in decreased weight or measure. Variations above the stated minimum shall not be unreasonably large.

(k) Where the statement does not express the minimum quantity:

(1) Variations from the stated weight or measure shall be permitted when caused by ordinary and customary exposure, after the cosmetic is introduced into interstate commerce, to conditions which normally occur in good distribution practice and which unavoidably result in change of weight or measure.

(2) Variations from the stated weight, measure, or numerical count shall be permitted when caused by unavoidable deviations in weighing, measuring, or counting individual packages which occur in good packing practice. But under this subparagraph variations shall not be permitted to such extent that the average of the quantities in the packages comprising a shipment or other delivery of the cosmetic is below the quantity stated, and no unreasonable shortage in any package shall be permitted, even though overages in other packages in the same shipment or delivery compensate for such shortage.

(l) The extent of variations from the stated quantity of the contents permissible under paragraphs (j) and (k) of this section in the case of each shipment or other delivery shall be determined by the facts in such case.

(m) A cosmetic shall be exempt from compliance with the requirements of clause (2) of section 602 (b) of the act if the quantity of the contents of the package, as expressed in terms applicable to such cosmetic under the provisions of paragraph (e) (2) of this section, is less than one-fourth ounce avoirdupois, or less than one-eighth fluid ounce, or (in case the units of the cosmetic can be easily counted without opening the package) less than six units.

(Sec. 602 (b), 52 Stat. 1054; 21 U. S. C. 362 (b))

§ 1.203 *Cosmetic; labeling requirements, form of stating.* (a) A word, statement, or other information required by or under authority of the act to appear on the label may lack that prominence and conspicuousness required by section 602 (c) of the act by reason (among other reasons) of:

(1) The failure of such word, statement, or information to appear on the part or panel of the label which is presented or displayed under customary conditions of purchase;

(2) The failure of such word, statement, or information to appear on two or more parts or panels of the label, each of which has sufficient space therefor, and each of which is so designed as to render it likely to be, under customary conditions of purchase, the part or panel displayed;

(3) The failure of the label to extend over the area of the container or package available for such extension, so as to provide sufficient label space for the prominent placing of such word, statement, or information;

(4) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space for any word, statement, design, or device which is not required by or under authority of the act to appear on the label;

(5) Insufficiency of label space (for the prominent placing of such word, statement, or information) resulting from the use of label space to give materially greater conspicuousness to any other word, statement, or information, or to any design or device;

(6) Smallness or style of type in which such word, statement, or information appears, insufficient background

contrast, obscuring designs or vignettes, or crowding with other written, printed, or graphic matter.

(b) (1) All words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear thereon in the English language.

(2) If the label contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label shall appear thereon in the foreign language.

(3) If the labeling contains any representation in a foreign language, all words, statements, and other information required by or under authority of the act to appear on the label or labeling shall appear on the labeling in the foreign language.

(Sec. 602 (c), 52 Stat. 1054; 21 U. S. C. 362 (c))

§ 1.204 *Cosmetic; labeling requirements; exemptions.* (a) Except as provided by paragraphs (b) and (c) of this section, a shipment or other delivery of a cosmetic which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from compliance with the labeling requirements of sections 601 (a) and 602 (b) of the act if:

(1) The person who introduced such shipment or delivery into interstate commerce is the operator of the establishment where such cosmetic is to be processed, labeled, or repacked; or

(2) In case such person is not such operator, such shipment or delivery is made to such establishment under a written agreement, signed by and containing the post-office addresses of such person and such operator, and containing such specifications for the processing, labeling or repacking, as the case may be, of such cosmetic in such establishment as will insure, if such specifications are followed, that such cosmetic will not be adulterated or misbranded within the meaning of the act upon completion of such processing, labeling, or repacking. Such person and such operator shall each keep a copy of such agreement until all such shipment or delivery has been removed from such establishments, and shall make such copies available for inspection at any reasonable hour to any officer or employee of the Department who requests them.

(b) An exemption of a shipment or other delivery of a cosmetic under paragraph (a) (1) of this section shall, at the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment, become void ab initio if the cosmetic comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed.

(c) An exemption of a shipment or other delivery of a cosmetic under paragraph (a) (2) of this section shall become void ab initio with respect to the person who introduced such shipment or delivery into interstate commerce upon refusal by such person to make available for inspection a copy of the agreement, as required by such clause.

(d) An exemption of a shipment or other delivery of a cosmetic under paragraph (a) (2) of this section shall expire:

(1) At the beginning of the act of removing such shipment or delivery, or any part thereof, from such establishment if the cosmetic comprising such shipment, delivery, or part is adulterated or misbranded within the meaning of the act when so removed; or

(2) Upon refusal by the operator of the establishment where such cosmetic is to be processed, labeled, or repacked, to make available for inspection a copy of the agreement, as required by such clause.

(Sec. 603, 52 Stat. 1054; 21 U. S. C. 363)

IMPORTS AND EXPORTS

AUTHORITY: §§ 1.315 to 1.322 issued under sec. 701, 52 Stat. 1055, as amended; 21 U. S. C. 371. Interpret or apply sec. 801, 52 Stat. 1058; 21 U. S. C. 381.

§ 1.315 *Definitions.* For the purposes of the regulations prescribed under section 801 (a), (b), and (c) of the Federal Food, Drug, and Cosmetic Act:

(a) The term "owner" or "consignee" means the person who has the rights of a consignee under the provisions of sections 483, 484, and 485 of the Tariff Act of 1930, as amended (19 U. S. C. 1483, 1484, 1485).

(b) The term "chief of district" means the chief of the district of the Food and Drug Administration having jurisdiction over the port of entry through which an article is imported or offered for import, or such officer of the district as he may designate to act in his behalf in administering and enforcing the provisions of section 801 (a), (b), and (c).

§ 1.316 *Notice of sampling.* When a sample of an article offered for import has been requested by the chief of district, the collector of customs having jurisdiction over the article shall give to the owner or consignee prompt notice of delivery of, or intention to deliver, such sample. Upon receipt of the notice, the owner or consignee shall hold such article and not distribute it until further notice from the chief of district or the collector of customs of the results of examination of the sample.

§ 1.317 *Payment for samples.* The Food and Drug Administration will pay for all import samples which are found to be in compliance with the requirements of the Federal Food, Drug, and Cosmetic Act. Billing for reimbursement should be made by the owner or consignee to the Food and Drug Administration district headquarters in whose territory the shipment was offered for import. Payment for samples will not be made if the article is found to be in violation of the act, even though subsequently brought into compliance under the terms of an authorization to bring the article into compliance or rendered not a food, drug, device, or cosmetic as set forth in § 1.319.

§ 1.318 *Hearing.* (a) If it appears that the article may be subject to refusal of admission, the chief of district shall give the owner or consignee a written notice to that effect, stating the reasons therefor. The notice shall specify a place and a period of time during which the owner or consignee shall have an opportunity to introduce testimony. Upon timely request, giving reasonable grounds therefor, such time and place may be changed. Such testimony shall be confined to matters relevant to the admissibility of the article, and may be introduced orally or in writing.

(b) If such owner or consignee submits or indicates his intention to submit an application for authorization to relabel or perform other action to bring the article into compliance with the act or to render it other than a food, drug, device, or cosmetic, such testimony shall include evidence in support of such application. If such application is not submitted at or prior to the hearing, the chief of district shall specify a time limit, reasonable in the light of the circumstances, for filing such application.

§ 1.319 *Application for authorization.* Application for authorization to relabel or perform other action to bring the article into compliance with the act or to render it other than a food, drug, device or cosmetic may be filed only by the owner or consignee, and shall:

(a) Contain detailed proposals for bringing the article into compliance with the act or rendering it other than a food, drug, device, or cosmetic.

(b) Specify the time and place where such operations will be carried out and the approximate time for their completion.

§ 1.320 *Granting of authorization.* (a) When authorization contemplated by § 1.319 is granted, the chief of district shall notify the applicant in writing, specifying:

(1) The procedure to be followed;

(2) The disposition of the rejected articles or portions thereof;

(3) That the operations are to be carried out under the supervision of an officer of the Food and Drug Administration or the Bureau of Customs, as the case may be;

(4) A time limit, reasonable in the light of the circumstances, for completion of the operations; and

(5) Such other conditions as are necessary to maintain adequate supervision and control over the article.

(b) Upon receipt of a written request for extension of time to complete such operations, containing reasonable grounds therefor, the chief of district may grant such additional time as he deems necessary.

(c) An authorization may be amended upon a showing of reasonable grounds therefor and the filing of an amended application for authorization with the chief of district.

(d) If ownership of an article covered by an authorization changes before the operations specified in the authorization have been completed, the original owner will be held responsible, unless the new owner has executed a bond and obtained a new authorization. Any authorization granted under this section shall supersede and nullify any previously granted authorization with respect to the article.

§ 1.321 *Bonds.* (a) The bonds required under section 801 (b) of the act may be executed by the owner or consignee on the appropriate form of a customs single-entry or term bond, containing a condition for the redelivery of the merchandise or any part thereof upon demand of the collector of customs and containing a provision for the performance of conditions as may legally be imposed for the relabeling or other action necessary to bring the article into compliance with the act or rendering it other than a food, drug, device, or cosmetic, in such manner as is prescribed for such bond in the customs regulations in force on the date of request for authorization. The bond shall be filed with the collector of customs.

(b) The collector of customs may cancel the liability for liquidated damages incurred under the above-mentioned provisions of such a bond, if he receives an application for relief therefrom, upon the payment of a lesser amount or upon such other terms and conditions as shall be deemed appropriate under the law and in view of the circumstances, but the collector shall not act under this regulation in any case unless the chief of district is in full agreement with the action.

§ 1.322 *Costs chargeable in connection with relabeling and reconditioning inadmissible imports.* The cost of supervising the relabeling or other action in connection with an import of food, drugs, devices, or cosmetics which fails to comply with the Federal Food, Drug, and Cosmetic Act shall be paid by the owner or consignee who files an application requesting such action and executes a bond, pursuant to section 801 (b) of the act, as amended. The cost of such supervision shall include, but not be restricted to, the following:

(a) Travel expenses of the supervising officer.

(b) Per diem in lieu of subsistence of the supervising officer when away from his home station, as provided by law.

(c) Services of the supervising officer, to be calculated at a flat rate of $4.00 per hour (which shall include administrative expense), except that such services performed by a customs officer and subject to the provisions of section 5 of the act of February 13, 1911, as amended (19 U. S. C. 267), shall be calculated as provided in that act.

(d) Services of analyst, to be calculated at a flat rate of $5.00 per hour (which shall include the use of the chemical laboratories and equipment of the Food and Drug Administration).

(e) The minimum charge for services of supervising officers and of analysts shall be not less than the charge for 1 hour, and time after the first hour shall be computed in multiples of 1 hour, disregarding fractional parts less than ½ hour.

ADMINISTRATIVE

§ 1.700 *Examinations and investigations; samples.* (a) (1) When any officer or employee of the Department collects a sample of a food, drug, or cosmetic for analysis under the act, the sample shall be designated as an official sample if records or other evidence is obtained by him or any other officer or employee of the Department indicating that the shipment or other lot of the article from which such sample was collected was introduced or delivered for introduction into interstate commerce, or was in or was received in interstate commerce, or was manufactured within a Territory. Only samples so designated by an officer or employee of the Department shall be considered to be official samples.

(2) For the purpose of determining whether or not a sample is collected for analysis, the term "analysis" includes examinations and tests.

(3) The owner of a food, drug, or cosmetic of which an official sample is collected is the person who owns the shipment or other lot of the article from which the sample is collected.

(b) When an officer or employee of the Department collects an official sample of a food, drug, or cosmetic for analysis under the act, he shall collect at least twice the quantity estimated by him to be sufficient for analysis, unless:

(1) The amount of the article available and reasonably accessible for sampling is less than twice the quantity so estimated;

(2) The cost of twice the quantity so estimated exceeds $10;

(3) The article is perishable;

(4) The sample is collected from a shipment or other lot which is being imported or offered for import into the United States;

(5) The sample is collected from a person named on the label of the article, or his agent, and such person is also the owner of the article;

(6) The sample is collected from the owner of the article, or his agent, and such article bears no label or, if it bears a label, no person is named thereon; or

(7) The analysis consists principally of rapid analytical procedures, organoleptic examination, or other field inspection examinations or tests, made at the place where the sample is collected or in a mobile or temporary laboratory. In addition to the quantity of sample prescribed above the officer or employee shall, if practicable, collect as part of the sample such further amount of the article as he estimates to be sufficient for use as exhibits in the trial of any case that may arise under the act based on the sample.

(c) After the Food and Drug Administration has completed such analysis of an official sample of a food, drug, or cosmetic as it determines, in the course of analysis and interpretation of analytical results, to be adequate to establish the respects, if any, in which the article is adulterated or misbranded within the meaning of the act, or otherwise subject to the prohibitions of the act, and has reserved an amount of the article it estimates to be adequate for use as exhibits in the trial of any case that may arise under the act based on the sample, a part of the sample, if any remains available, shall be provided for analysis, upon written request, by any person named on the label of the article, or the owner thereof, or the attorney or agent of such person or owner, except when:

(1) After collection, the sample or remaining part thereof has become decomposed or otherwise unfit for analysis, or

(2) The request is not made within a reasonable time before the trial of any case under the act, based on the sample, to which such person or owner is a party. The person, owner, attorney, or agent who requests the part of sample shall specify the amount desired. A request from an owner shall be accompanied by a showing of ownership, and a request from an attorney or agent by a showing of authority from such person or owner to receive the part of sample. When two or more requests for parts of the same sample are received the requests shall be complied with in the order in which they were received so long as any part of the sample remains available therefor.

(d) When an official sample of a food, drug, or cosmetic is the basis of a notice given under section 305 of the act, or of a case under the act, and the person to whom the notice was given, or any person who is a party to the case, has no right under paragraph (c) of this section to a part of the sample, such person or his attorney or agent may obtain a part of the sample upon request accompanied by a written waiver of right under such paragraph (c) from each person named on the label of the article and owner thereof, who has not exercised his right under such paragraph (c). The operation of this paragraph shall be subject to the exceptions, terms, and conditions prescribed in paragraph (c) of this section.

(e) The Food and Drug Administration is authorized to destroy:

(1) Any official sample when it determines that no analysis of such sample will be made;

(2) Any official sample or part thereof when it determines that no notice under section 305 of the act, and no case under the act, is or will be based on such sample;

(3) Any official sample or part thereof when the sample was the basis of a notice under section 305 of the act, and when, after opportunity for presentation of views following such notice, it determines that no other such notice, and no case under the act, is or will be based on such sample;

(4) Any official sample or part thereof when the sample was the basis of a case under the act which has gone to final judgment, and when it determines that no other such case is or will be based on such sample;

(5) Any official sample or part thereof if the article is perishable;

(6) Any official sample or part thereof when, after collection, such sample or part has become decomposed or otherwise unfit for analysis;

(7) That part of any official sample which is in excess of three times the quantity it estimates to be sufficient for analysis.

(Secs. 701 (a), (b), 52 Stat. 1055, 1057; 21 U. S. C. 371 (a), 372 (b))

RULES OF PRACTICE FOR HEARINGS

AUTHORITY: §§ 1.701 to 1.715 issued under sec. 701, 52 Stat. 1055; 21 U. S. C. 371.

DEFINITIONS

§ 1.701 *Definitions.* As used in §§ 1.701–1.715:

(a) The term "act" means the Federal Food, Drug, and Cosmetic Act, approved June 25, 1938 (52 Stat. 1040, as amended; 21 U. S. C. 301–392).

(b) The term "Department" means the Department of Health, Education, and Welfare of the United States.

(c) The term "Secretary" means the Secretary of Health, Education, and Welfare.

(d) The term "Federal Register" means the publication provided for by the Federal Register Act of July 26, 1935 and acts supplementary thereto and amendatory thereof (49 Stat. 500, 50 Stat. 304, sec. 202, 53 Stat. 1435, 56 Stat. 1045, 61 Stat. 451; 44 U. S. C. Chapter 8B).

(e) The term "person" includes an individual, partnership, corporation, and association.

(f) The term "hearing clerk" means the hearing clerk of the Department.

HEARINGS AND NOTICE THEREOF

§ 1.702 *Hearings under section 701 (e) of the act, except hearings with reference to regulations under section 404 (a) of the act.* The Secretary, on his own initiative or upon an application of any interested industry or substantial portion thereof stating reasonable grounds therefor, shall hold a public hearing upon a proposal to issue, amend, or repeal any regulation contemplated by any of the following sections of the act: 401, 403 (j), 406 (a) and (b), 501 (b), 502 (d), (h), 504, and 604.

§ 1.703 *Notice of hearing.* The Secretary shall give notice of the hearing by filing the same with the Archivist of the United States for publication in the Federal Register. The notice shall set forth the proposal in general terms and shall specify the time, which shall not be less than 30 days after the date of the notice, and the place for the public hearing.

§ 1.704 *Designation and powers of presiding officer.* (a) Each such hearing shall be conducted by a presiding officer, who shall be the Secretary or such officer or employee of the Secretary as the Department may designate for the purpose. Any such designation may be made or revoked by the Secretary at any time. Such hearing shall be conducted in an informal but orderly manner in accordance with the rules in §§ 1.701–1.715, and, where such rules are inapplicable or incomplete, in accordance with the directions of the presiding officer. The presiding officer shall have power to administer oaths, examine witnesses, and receive evidence, and to rule upon the admissibility of evidence and other matters that arise in the course of the hearing, but, except where the presiding officer is the Secretary, shall have no power to decide any motion which involves final determination of the merits of the proceeding.

(b) The hearing shall be held at the time and place set forth in the notice of the hearing, but may at such time and place be continued from day to day and adjourned to a later day or to a different place, within the city designated in the notice, without notice other than the announcement thereof by the presiding officer at the hearing.

PROCEDURE AT HEARING

§ 1.705 *Appearances.* At the hearing, any interested person shall be given an opportunity to appear, either in person or through his authorized representative, and to be heard with respect to matters relevant and material to the proposal. Any interested person who desires to be heard in person at any hearing under the rules in §§ 1.701–1.715 shall file with the presiding officer a written appearance setting forth his name, address and occupation. If such person desires to be heard through a representative, such person or such representative shall file with the presiding officer a written appearance setting forth the authority for such representative and the names, addresses, and occupations of such person and such representative. Any such person or such representative shall give such other information respecting his appearance as the presiding officer may request. All present at the hearing shall conform to all reasonable standards of orderly and ethical conduct.

§ 1.706 *Order of procedure.* (a) The presiding officer shall have noted on the record his designation as presiding officer and the notice of the hearing as filed with the Archivist of the United States. This shall be done by filing as an exhibit for the record a copy of the Federal Register containing such designation and such notice. If the designation has not been published in the Federal Register, the presiding officer shall file as an exhibit the order of the Secretary designating him to preside.

(b) To promote orderliness and clarity of the record, evidence shall be received with respect to the subject matter of the hearing in the following order, except as the presiding officer otherwise may permit:

(1) Evidence with respect to the proposal in general, including such matters as its historical background, the reason for the proposal, and its probable effect. No evidence shall be introduced at this stage of the hearing as to any specific provision of the proposal.

(2) Evidence with respect to specific terms of the proposal, which shall be read and considered section by section in a sequence to be determined by the presiding officer. Suggestions to add to, delete, or alter any portions of a given section of the proposal shall be made as consideration of such section is reached and, insofar as practicable, shall be submitting in writing.

(3) At each stage of the hearing, whether general or specific, evidence shall be received first in support of the proposal, followed by the evidence opposing the proposal.

§ 1.707 *Submission and receipt of evidence.* (a) Each witness shall, before proceeding to testify, be sworn or make affirmation.

(b) When necessary in order to prevent undue prolongation of the hearing, the presiding officer may limit the number of times any witness may testify to the same matter or the repetitious examination and cross-examination of witnesses, or the amount of corroborative or cumulative evidence.

(c) The presiding officer shall admit only relevant and material evidence.

(d) Opinion evidence shall be admitted when the presiding officer is satisfied that the witness is properly qualified.

(e) Affidavits, if relevant and material, shall be received and marked as exhibits, provided they are filed with the presiding officer on or before the date of the opening of the hearing. Every interested person shall be permitted to examine all affidavits which have been so filed and to file counter-affidavits with the presiding officer, within a period of time, to be fixed by the presiding officer, not more than 5 days following the close of the hearing. In any event, the Secretary will consider the lack of opportunity for cross-examination in determining the weight to be attached to statements made in the form of affidavits.

(f) If any person objects to the admission or rejection of any evidence, or other limitation of the scope of any examination or cross-examination, he shall state briefly the grounds of such objection, and the transcript shall not include argument or debate thereon except as ordered by the presiding officer. Any such objection shall be made before the presiding officer in order subsequently to be relied upon in the proceeding. A ruling of the presiding officer on any such objection shall be a part of the transcript, together with such offer of proof as has been made.

(g) Samples may be displayed at the hearing and may be described for purposes of the record but shall not be admitted in evidence as exhibits.

§ 1.708 *Transcript of the testimony.* Testimony given at a hearing shall be reported verbatim. All written statements, charts, tabulations, and similar data offered in evidence at the hearing shall be marked for identification and, upon a showing satisfactory to the presiding officer of their authenticity, relevancy, and materiality, shall be received and marked as exhibits in evidence. Such exhibits (including affidavits) shall, if practicable, be submitted in quintuplicate and in documentary form. In case the required number of copies are not made available, the presiding officer shall exercise his discretion as to whether said exhibit shall when practicable be read in evidence or whether additional copies shall be required to be submitted within a time to be specified by the presiding officer. Where the testimony of a witness refers to a statute, or to a report or document, the presiding officer shall, after inquiry relating to the identification of such statute, report, or document, determine whether the same shall be produced at the hearing and physically be made a part of the evidence as an exhibit or whether it shall be incorporated into the evidence by reference. Where relevant and material matter offered in evidence is embraced in a report or document containing immaterial and irrelevant matter, such immaterial and irrelevant matter shall be excluded and shall be segregated insofar as practicable, subject to the direction of the presiding officer.

§ 1.709 *Oral and written arguments.* (a) Unless the presiding officer shall issue an announcement at the hearing authorizing oral argument before him, it shall not be permitted.

(b) The presiding officer shall announce at the hearing a reasonable period within which interested persons may file written arguments based solely upon the evidence received at the hearing, citing the page or pages of the transcript of the testimony where such evidence occurs.

§ 1.710 *Filing the record of the hearing.* As soon as practicable after the close of the hearing, the complete record of the hearing shall be filed in the office of the hearing clerk. The record of the hearing shall include the transcript of the testimony, including any exhibits and together with any written arguments that may have been filed with the presiding officer.

§ 1.711 *Copies of the record of the hearing.* The Department will make provisions for a stenographic record of the testimony and for such copies of the transcript thereof as it requires for its own purposes. Any person desiring a copy of the record of the hearing or of any part thereof shall be entitled to the same upon application to the hearing clerk and upon payment of the costs thereof. Suggested corrections to transcripts of the testimony shall be considered only if offered within a period (to be fixed by the presiding officer) of not more than 3 days following the completion of the testimony, for which purpose the record shall be kept open for such additional period. The presiding officer shall have authority to act upon such suggested corrections.

ISSUANCE OF ORDER

§ 1.712 *Proposed order.* The Secretary, within a reasonable time after the filing of the record of the hearing, will issue his proposed order, which shall be served upon the interested persons whose appearances were entered at the hearing by publication in the FEDERAL REGISTER or by mailing a copy of the proposed order to each of such persons by registered mail: *Provided, however,* That if, after examination of the record of the hearing, the Secretary finds that no controversy with respect to the subject of the hearing exists between the persons who appeared thereat, and that such action will promote the purposes of the act, the Secretary will issue a final order in lieu of issuing a proposed order in accordance with this section.

§ 1.713 *Exceptions.* Within a reasonable time, which shall be specified in the proposed order but shall not exceed 20 days from the time of the issuance of such order, any interested person whose appearance was filed at the hearing may file exceptions to the proposed order. The exceptions shall point out with particularity the alleged errors in said proposed order, and shall contain a specific reference to the page of the transcript of the testimony or to the exhibit on which each exception is based. Such exceptions may be accompanied by a memorandum brief in support thereof.

§ 1.714 *Final order.* The Secretary thereafter will issue his final order. A duplicate original thereof shall thereupon be filed with the Archivist of the United States and published in the FEDERAL REGISTER. A duplicate original thereof shall also be filed with the hearing clerk for public inspection.

PUBLIC NOTICE OF REGULATIONS

§ 1.715 *Public notice of regulations.* Public notice of the issuance of the foregoing rules of practice for hearings in §§ 1.701–1.714 shall be given by publishing the same in the FEDERAL REGISTER.

PART 3—STATEMENTS OF GENERAL POLICY OR INTERPRETATION

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3.42 Pesticide chemicals; additional extended dates on which statute shall become fully effective; denial of requests for extensions.
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3.45 Sterilization of drugs by irradiation.

AUTHORITY: §§ 3.2 to 3.45 issued under sec. 701, 52 Stat. 1055; 21 U. S. C. 371. Statutory provisions interpreted or applied are cited to text in parentheses.

§ 3.2 *Notice to packers and shippers of shelled peanuts.* Investigations by the Food and Drug Administration have shown that a number of interstate shipments of shelled peanuts in bags holding from approximately 100 to 125 pounds each have failed to bear labeling as required by the terms of the Federal Food, Drug, and Cosmetic Act.

Shelled peanuts in sacks, whether or not shipped in carload lots, should bear the following information required by the law on food in package form:

(a) The name of the product.

(b) An accurate statement of net weight.

(c) The name and place of business of the packer or distributor.

This information should be conspicuously set forth. It may be printed or stenciled on each bag or, if desired, placed on tags which are securely attached to each bag.

The net weight marked on the bags must be the correct net weight of the peanuts at the time they are delivered to the carrier for interstate shipment. The tare weight of the bag should not be included in the weight declaration.

§ 3.3 *Notice to manufacturers, packers, and distributors of glandular preparations.* Under date of December 4, 1941, in a notice to manufacturers of glandular preparations, the Food and Drug Administration expressed the opinion that preparations of inert glandular materials intended for medicinal use should, in view of the requirement of section 201 (n) of the Federal Food, Drug, and Cosmetic Act (52 Stat. 1041; 21 U. S. C. 321 (n)), be labeled with a statement of the material fact that there is no scientific evidence that the articles contain any therapeutic or physiologically active constituents. Numerous preparations of such inert glandular materials were subsequently marketed with disclaimers of the type suggested. The term "inert glandular materials" means preparations incapable of exerting an action or effect of some significant or measurable benefit in one way or another, i. e., in the diagnosis, cure, mitigation, treatment, or prevention of disease, or in affecting the structure or any function of the body.

Manufacturers have heretofore taken advantage of regulation (b) under section 502 (f) of the act (§ 1.106 (b) of this chapter), permitting omission of directions for use where the so-called "prescription only" legend was placed upon the labels. This regulation was amended, effective October 10, 1945. Among the conditions now authorizing the omission of directions for use, § 1.106 (b) (3) of this chapter, is the following: "Information adequate for the use of such drug * * * by physicians, dentists, or veterinarians, as the case may be, is readily available." Obviously, information adequate for the use of a glandular preparation which is inert is not available to physicians, dentists, or veterinarians.

The Department of Health, Education, and Welfare is of the opinion that inert glandular materials may not be exempted from the requirements of section 502 (f) (1) of the act that they bear adequate directions for use; and, accordingly, that their labeling must include, among other things, representations as to the conditions for which such articles are intended to be used or as to the structure or function of the human body that they are intended to affect. Since any such representations offering these articles for use as drugs would be false or misleading, such articles will be considered to be misbranded if they are distributed for use as drugs.

The amended regulations provide also that in the case of drugs intended for parenteral administration there shall be no exemption from the requirement that their labelings bear adequate directions for use. Such inert glandular materials for parenteral use are therefore subject to the same comment as applies to those intended for oral administration.

§ 3.4 *Notice to manufacturers, packers, and distributors of drugs for internal use which contain mineral oil.* In the past few years research studies have altered medical opinion as to the usefulness and harmfulness of mineral oil in the human body. These studies have indicated that when mineral oil is used orally near mealtime it interferes with absorption from the digestive tract of provitamin A and the fat-soluble vitamins A, D, and K, and consequently interferes with the utilization of calcium and phosphorus, with the result that the user is left liable to deficiency diseases. When so used in pregnancy it predisposes to hemorrhagic disease of the newborn.

There is accumulated evidence that the indiscriminate administration of mineral oil to infants may be followed by aspiration of the mineral oil and subsequent "lipoid pneumonia."

In view of these facts, the Department of Health, Education, and Welfare will regard as misbranded under the provisions of the Federal Food, Drug, and Cosmetic Act a drug for oral administration consisting in whole or in part of mineral oil, the labeling of which encourages its use in pregnancy or indicates or implies that such drug is for administration to infants.

It is also this Department's view that the act requires the labelings of such drugs to bear a warning against consumption other than at bedtime and against administration to infants. The following form of warning is suggested: "Caution: To be taken only at bedtime. Do not use at any other time or administer to infants, except upon the advice of a physician."

This statement of interpretation does not in any way exempt mineral oil or preparations containing mineral oil from complying in all other respects with the requirements of the Federal Food, Drug, and Cosmetic Act.

§ 3.5 *Notice to manufacturers, packers, and distributors of gauze bandages.* The twelfth revision of the United States Pharmacopeia established a packaging specification standard for adhesive absorbent gauze (adhesive absorbent compress) which read: "Adhesive absorbent gauze must be packaged individually in such manner that the sterility is maintained until the individual package is opened for use, and the individual packages must be grouped in a second protective container." This specification, with slight modifications in the wording, appears in the thirteenth revision of the United States Pharmacopeia, which is now official.

At the time the standard was first promulgated representations were made to the Food and Drug Administration that, due to the existence of war priorities, it was impossible for manufacturers to obtain the machinery needed to wrap the bandages individually. In view of the priority situation existing at that time, the Administration informed manufacturers generally that until conditions changed no legal actions would be inaugurated under the provisions of the Federal Food, Drug, and Cosmetic Act based solely on the failure to wrap adhesive gauze bandages individually.

Recent investigations have revealed that most manufacturers have obtained the machinery needed for the individual wrapping of such bandages or have been promised early delivery of such machinery. It will be the purpose of the Department of Health, Education, and Welfare to recommend legal actions in instances where United States Pharmacopeia packaging requirements are not complied with after July 1, 1948.

§ 3.6 *Notice to importers of Peruvian canned fish.* In collaboration with the United States Department of State and officials of the Government of Peru, the Food and Drug Administration of the Department of Health, Education, and Welfare has made a study in Peru of the canning of bonito and tuna packed for exportation to the United States. The fish known in Peru as bonito constitutes a major portion of the pack. Representative specimens of Peruvian bonito have been identified as the species Sarda chilensis. This confirms previous information that the species of fish constituting the commercial bonito fishery in Peru is the same species of bonito that has been packed in this country in small quantities and sold as bonito, for many years. Minor quantities of another bonito, Sarda velox, are apparently caught in Peruvian waters but do not enter the commercial pack to any significant degree. The bonitos, Sarda chilensis and Sarda velox, are not classified as tuna and under the provisions of the Federal Food, Drug, and Cosmetic Act have never been legally labeled as tuna, but must be labeled as "bonito" or "bonito fish."

Two species of tuna, "skipjack" (Katsuwonus pelamis) and "yellowfin" (Thunnus macropterus), are commercially canned in Peru but constitute a relatively small proportion of the Peruvian pack of canned fish exported to the United States.

Information developed during the investigation in Peru shows that the bonito (Sarda chilensis) can be readily distinguished from the tunas. Consequently no difficulty should be encountered by packers in keeping separate the fish in the two classifications and in properly labeling the canned product before shipment.

The provisions of the Federal Food, Drug, and Cosmetic Act require that importations of canned bonito and canned tuna, when offered for entry into the United States, must bear labels designating the product as "bonito" or as "tuna", as the case may be. Shipments that are unlabeled or mislabeled when offered for entry must be detained and are subject to refusal of admission, with consequent exportation or destruction.

§ 3.7 *Notice to manufacturers, packers, and distributors of veterinary preparations and animal feeds.* A number of products have been developed to promote fattening, increase milk or egg production, or effect other physiological changes in farm animals. Many of these compounds contain as active ingredients substances the toxicity of which is known to be of a high order. For example, thiouracil, a very potent drug, has been proposed for use to promote fattening. When such substances are added to food they render the food adulterated under section 402 (a) of the Federal Food, Drug, and Cosmetic Act.

The Department of Health, Education, and Welfare regards sections 402 (a) (2) and 406 of the act as clear enunciations of congressional intent to deny the channels of interstate commerce to food containing added poisonous or deleterious ingredients which are unnecessary in its production or which can be avoided by good manufacturing practice.

Since these compounds are intended to affect the structure or function of the body of animals and have not been previously used for such purposes, they are regarded as new drugs, requiring the submission of adequate evidence of their safety, as required by section 505 of the act, before being marketed in interstate commerce.

In considering a new-drug application for a product intended to effect physiological changes in farm animals, the Department of Health, Education and Welfare will regard the absence of satisfactory evidence showing that the meat or other food obtained from animals fed the drug is entirely free of any poisonous or deleterious ingredient resulting therefrom at the time of marketing as ground for refusal to make the application effective.

§ 3.8 *Notice to manufacturers, packers, and distributors of penicillin-containing drugs for veterinary use.* Since the release on October 5, 1945, of the notice to manufacturers and distributors of veterinary penicillin and a circular entitled "Indications, Directions and Precautions Suggested for Inclusion in the Labeling of Sodium and Calcium Penicillin for Veterinary Use" and the supplemental material released on April 25, 1946, much additional information has accumulated relative to the use of penicillin in animals. However, the knowledge concerning the efficacy and limitations of penicillin for treating various disease conditions of animals is far from being complete. Therefore this statement, which is intended to supersede previously released information on the labeling of penicillin-containing drugs for veterinary use, is in the nature of a tentative guide to be used in conjunction with the penicillin regulations for labeling penicillin for veterinary use. As the knowledge of the efficacy and limitations of penicillin for treating animals is expanded there will be further releases relating to the labeling of such drugs. It is believed, however, that at the present time claims made in the labeling of penicillin intended for veterinary use should not exceed those suggested in this section.

Penicillin, under laboratory conditions, has pronounced potency against a wide range of organisms, including the following of interest to veterinarians: most strains of streptococci, staphylococci, clostridia, corynebacteria, Bacillus anthracis, Actinomyces bovis, Erysipelothrix rhusiopathiae, and leptospira. Penicillin is ineffective in infections caused by gram-negative bacilli, viruses, and occasional resistant strains of organisms which are usually regarded as susceptible to penicillin.

(a) *Indications.* There is conclusive scientific evidence establishing the therapeutic efficacy of penicillin for bovine mastitis caused by Streptococcus agalactiae. Good results have been reported in the use of penicillin for mastitis caused by strains of Streptococcus dysgalactiae. Results of treatment are no more than fair in mastitis caused by Streptococcus uberis and staphylococci; poor in cases caused by corynebacteria. Mastitis caused by colon bacilli does not respond to penicillin therapy. Reliable reports provide a supportive basis for recommending the use of penicillin for the following disease conditions: leptospirosis of dogs, osteomyelitis, peritonitis, strangles of horses, equine pneumonia, tetanus in the very early stage (with antitoxin), calf pneumonia, calf diphtheria, pyelonephritis in cattle, blackleg, malignant edema, anthrax in the very early stage, metritis, bovine actinomycosis, swine erysipelas in turkeys, and superficial infections of the skin caused by penicillin-sensitive organisms. It should be remembered that proper use of effective therapy depends on an accurate diagnosis of the disease condition to be treated.

(b) *Methods of administration*—(1) *By injection.* Deep intramuscular injection is the route of choice when using the parenteral forms of penicillin for systemic therapy. Subcutaneous injections are apt to be painful and are therefore usually avoided. When penicillin in oil or penicillin in oil and wax is injected care should be taken that the needle is not in a blood vessel before discharging the contents of the syringe.

(2) *By mouth.* Since penicillin is inactivated by gastric secretion, it cannot be given by mouth unless precautions are taken to neutralize the process in the stomach. This may be accomplished through the use of buffered penicillin tablets given at least ½ hour before and not less than 2 hours after eating. The therapeutic efficacy of these tablets will vary in different individuals and according to the amount of active penicillin absorbed. As a general rule, the amount of penicillin required for effective therapy when given by mouth is five times the amount required by injection. With the possible exception of small-animal practitioners, veterinarians will probably find it impracticable to use penicillin in this form. Buffered penicillin tablets may be of value in some cases in which it is not possible to administer the drug by injection at the required intervals and in others after the disease has been brought under control by penicillin injections, and it is desirable to continue the use of the drug. The tablets may be given alone or as a supplement to parenteral therapy. In all serious conditions, however, parenteral administration is the recommended route.

(3) *By topical application.* Topical application includes direct injection of penicillin suspended in suitable vehicles into udders through the teat canal, into abscesses, joint capsules, body cavities, the spinal canal, and direct application to the skin and eyes. The underlying purpose of this method is to insure effective therapeutic concentrations of the drug in local areas of infection. In many instances it may be used as an adjunct to parenteral injections. However, after parenteral injection penicillin does not penetrate readily to the eyes, into spinal fluid, or, unless in extremely high unitage, into the milk. Therefore the topical method appears to be the only practicable one of treating local infections involving the eyes, spinal canal, or udder.

(c) *Dosage*—(1) *Systemic infections.* For therapy of systemic infections caused by most strains of penicillin-sensitive organisms a minimum of 2,000 units per pound of body weight should be administered, preferably by intramuscular injection. Further information concerning this recommendation may be obtained by request from the Food and Drug Administration. The required dosage of water-soluble salts of penicillin dissolved in proper aqueous solvents should be repeated every 3 to 4 hours to establish and maintain effective therapeutic concentrations of the drug in the body fluids and tissues. The necessary amount of penicillin in oil and wax should be given every 12 hours. The indicated quantity of procaine penicillin in oil or of certain of the newer certifiable repository penicillin products may be given as infrequently as once every 24 hours or longer. However, severe infections or infections caused by less sensitive organisms may require up to double the minimum dosage or more frequent injections or both. Since the objective of penicillin therapy is to bring the infection under control as quickly as possible, the minimum dosage or frequency of injection or both should be increased materially in all conditions known to be caused by sensitive organisms if no definite indication of clinical improvement is noticed 12 to 14 hours after the initial injection.

(2) *Bovine Streptococcus agalactiae mastitis.* Effective treatment of udders infected with penicillin-sensitive organisms depends on maintaining therapeutically effective concentrations of penicillin in the area of infection. Available experimental data indicate that the following methods for introducing adequate amounts of the drug into infected quarters can be depended upon to overcome the infection in a majority (75 percent or more) of Streptococcus agalactiae mastitis cases:

(i) Aqueous solutions (sodium, calcium, or crystalline penicillin dissolved in sterile distilled water):

(*a*) Inject 25,000 to 30,000 units under aseptic conditions through the teat canal into each infected quarter. Repeat after each milking or once every 12 hours until five to seven injections have been made. One repeat injection may be sufficient in the chronic form without induration.

(*b*) In cows producing up to 40 pounds of milk per day a total of 100,000 units per infected quarter administered as five injections of 20,000 units each at intervals of 12 hours or as four injections of 25,000 units each at intervals of 24 hours. In cows producing more than 40 pounds of milk per day or in acute cases a total of 200,000 units per infected quarter administered as four injections of 50,000 units each at intervals of 24 hours. It may be desirable to skip one milking after the last injection in the series to prolong a therapeutic concentration of penicillin in the treated quarters. Volume of vehicle should be adequate to favor immediate distribution throughout the cistern area. Usually 50 cc. is adequate.

(*c*) Large udders: First day, 200,000 units per infected quarter; second and third days, 100,000 units per infected quarter each day. Small to moderate-sized udders: First day, 100,000 units per infected quarter; second and third days, 50,000 units per infected quarter each day. All quarters infected with Streptococcus agalactiae at the time of drying off should be infused with 100,000 to 200,000 units sometime during the dry period, preferably during the interval between 2 weeks after the last milking and 3 weeks before parturition.

(ii) Emulsified solutions (soluble salts of penicillin dissolved in oil and water emulsified with lanolin derivatives): Inject 100,000 units under aseptic conditions through the teat canal into each infected quarter. Repeat treatment if subsequent bacteriological examination shows infection to be still present.

(iii) Bougies (25,000 or more units of sodium, calcium, potassium, or procaine penicillin in a milk-soluble base shaped in slender, elongated form to permit easy insertion into the milk cistern of the udder through the teat canal). Aseptically insert one bougie into each infected quarter after each milking for as long as the infection persists.

(iv) Oil and wax suspensions (calcium or crystalline penicillin in refined peanut or sesame oil and white wax) and ointments (calcium or crystalline penicillin in an ointment base suitable for udder instillation). In view of the scarcity of information concerning this use of such products, basic directions for use may be different in individual cases. Adequacy of directions as a whole depends primarily on the penicillin potency of each product and the nature of supportive data.

(3) *General.* Whenever practicable, accurate diagnosis should be established by identification of the causative organism. No case of mastitis should be considered cured unless bacteriological examination of the milk taken from treated quarters approximately 3 weeks after the last application of penicillin shows the absence of causative organisms. Augmenting penicillin therapy with proper surgical treatment yields best results when treating abscesses, empyema, suppurative arthritis, and infections of body cavities and joints caused by penicillin-sensitive organisms. Collections of pus should be removed prior to each local application of 25,000 to 50,000 units of penicillin in sterile aqueous solution two to three times every 24 hours. Sterile dressings, saturated with an aqueous solution containing at least 1,000 units of penicillin per milliliter, applied one or more times per day as the condition indicates, may be effective for treating superficial infections of the skin caused by penicillin-sensitive organisms. If indicated, supplement local therapy with systemic medication.

(d) *Precautions.* If reactions occur which cannot be adequately controlled and are more serious than the condition being treated, use of the drug should be discontinued.

§ 3.9 *Notice to manufacturers, packers, and distributors of salt substitutes.* The recent reported poisonings from salt substitutes containing lithium chloride have focused attention upon this entire field. Salt substitutes have been regarded in the past as special dietary foods. They are also drugs, since they are employed in the mitigation and treatment of disease. There is considerable doubt as to the safety of unrestricted use of any salt substitute in the presence of cardio-vascular-renal disease and a low sodium diet. Consequently, the Department of Health, Education, and Welfare believes that each salt substitute is a new drug within the meaning of section 201 (p) of the Federal Food, Drug, and Cosmetic Act. The interstate distribution of each salt substitute should be discontinued until a new-drug application has been filed and has become effective with respect to the substitute.

§ 3.10 *Notice to manufacturers and users in food products of monosodium glutamate.* In the light of information now before the Food and Drug Administration on the manner of use of monosodium glutamate in foods, this Agency is not disposed to maintain the position previously expressed by it on April 11, 1940, in a trade correspondence letter designated as TC 233 that monosodium glutamate be designated as an artificial flavoring on labels of foods to which it is added. Where it is used as an ingredient in a food for which a standard of identity has not been promulgated under the Federal Food, Drug, and Cosmetic Act, its presence should be declared on the label by its common or usual name, monosodium glutamate, in compliance with section 403 (i) (2) of the act. Since none of the standards of identity for food so far promulgated under section 401 provide for the inclusion of monosodium glutamate as an optional ingredient, this substance may not be used in such standardized foods unless and until the appropriate standards are amended after hearing. If in any case the addition of monosodium glutamate has the effect of concealing damage or inferiority, or of making the article appear to be of better or greater value than it is, the article would be classed as adulterated regardless of labeling.

§ 3.11 *Notice to manufacturers, packers, and distributors of estrogenic hormone preparations.* Some drug preparations fabricated wholly or in part from alpha-estradiol and labeled as to potency in terms of international units or in terms of international units of estrone activity have been marketed. The international unit of the estrus-producing hormone was established by the International Conference on the Standardization of Sex Hormones at London, England, on August 1, 1932. This unit was defined as "the specific estrus-producing activity contained in 0.1 gamma (=0.0001 mg.) of the standard" hydroxyketonic hormone found in urine (estrone). The International Conference declared that it did not recommend the determination of the activity of non-hydroxyketonic forms of estrogenic hormones in units of estrone because of the varying ratios between the activity of such non-hydroxyketonic estrogenic hormones and estrone, when measured by different methods on test animals. There is no international unit for measuring the activity of alpha-estradiol and no accepted relationship between its activity and that of estrone, either in test animals or in humans. The declaration of potency of alpha-estradiol in terms of international units or in terms of international units of estrone activity is therefore considered misleading, within the meaning of 21 U. S. C. 352 (a). The declaration of the alpha-estradiol content of an estrogenic hormone preparation in terms of weight is considered appropriate.

§ 3.12 *Temporary permits for interstate shipment of experimental packs of food varying from the requirements of definitions and standards of identity.* (a) The Department of Health, Education, and Welfare recognizes that appropriate investigations of potential advances in food technology sometimes require tests in interstate markets of the advantages to and acceptance by consumers of variations in foods from applicable definitions and standards of identity prescribed under section 401 of the Federal Food, Drug, and Cosmetic Act.

(b) It is the purpose of the Department to permit such tests where they are necessary to the completion or conclusiveness of an otherwise adequate investigation and where the interests of consumers are adequately safeguarded. The Department will therefore refrain from recommending regulatory proceedings under the act on the charge that a food does not conform to an applicable standard, if the person who introduces or causes the introduction of the food into interstate commerce holds an effective permit from the Secretary providing specifically for those variations in respect to which the food fails to conform to the applicable definition and standard of identity.

(c) Any person desiring a permit may file with the Secretary a written application in triplicate containing as part thereof the following:

(1) Name and address of the applicant.

(2) A statement of whether or not the applicant is regularly engaged in producing the food involved.

(3) A reference to the applicable definition and standard of identity (citing applicable section of regulations).

(4) A full description of the proposed variation from the standard.

(5) The basis upon which the food so varying is believed to be wholesome and nondeleterious.

(6) The amount of any new ingredient to be added; the amount of any ingredient, required by the standard, to be eliminated; any change of concentration not contemplated by the standard; or any change in name that would more appropriately describe the new product under test. If such new ingredient is not a commonly known food ingredient, a description of its properties and basis for concluding that it is not a deleterious substance.

(7) The purpose of effecting the variation.

(8) A statement of how the variation is of potential advantage to consumers.

(9) The labeling proposed to be used for the food so varying.

(10 The period during which the applicant desires to introduce such food into interstate commerce, with a statement of the reasons supporting the need for such period.

(11) The probable amount of such food that will be distributed.

(12) The areas of distribution.

(13) The address at which such food will be manufactured.

(14) A statement of whether or not such food has been or is to be distributed in the State in which it was manufactured.

(15) If it has not been or is not to be so distributed, a statement showing why.

(16) If it has been or is to be so distributed, a statement of why it is deemed necessary to distribute such food in other States.

(d) The Secretary may require the applicant to furnish samples of the food varying from the standard and to furnish such additional information as may be deemed necessary for action on the application.

(e) If the Secretary concludes that the variation may be advantageous to consumers and will not result in failure of the food to conform to any provision of the act except section 403 (g), a permit shall be issued to the applicant for interstate shipment of such food. The terms and conditions of the permit shall be those set forth in the application with such modifications, restrictions, or qualifications as the Secretary may deem necessary and state in the permit.

(f) The terms and conditions of the permit may be modified at the discretion of the Secretary or upon application of the permittee during the effective period of the permit.

(g) The Secretary may revoke a permit for cause, which shall include but not be limited to the following:

(1) That the permittee has introduced a food into interstate commerce contrary to the terms and conditions of the permit.

(2) That the application for a permit contains an untrue statement of a material fact.

(3) That the need therefor no longer exists.

(h) During the period within which any permit is effective, it shall be deemed to be included within the terms of any guaranty or undertaking otherwise effective pursuant to the provisions of section 303 (c) of the act.

(i) If an application is made for an extension of the permit, it shall be accompanied by a description of experiments conducted under the permit, tentative conclusions reached, and reasons why further experimental shipments are considered necessary.

(Secs. 401, 403, 52 Stat. 1046, 1047; 21 U. S. C. 341, 343)

§ 3.13 *Supplying pharmacists with indications and dosage of drugs.* (a) This Department is aware of statements that the regulations covering prescription drugs prevent the manufacturer from sending the pharmacist data he needs on indications and dosage in exercising his important professional function of checking against possible mistakes in the prescription.

(b) These regulations emphasize the importance of the profession of pharmacy; they are not intended to deprive the pharmacist of information necessary to the discharge of his professional duty of insuring the integrity of the drugs he dispenses on prescription.

(c) To discourage attempts at self-medication with drugs which the layman cannot safely and effectively use without the physician's guidance and which therefore should be dispensed only on doctor's orders, the regulations provide that the labeling of such drugs shall not bear indications or directions, except that the prescription package should bear the directions specified in the prescription. The law defines labeling as written, printed, or graphic matter accompanying the drug.

(d) The courts have given a broad interpretation to the definition of labeling, holding it to cover all pamphlets and the like used to inform consumers what the drug is for and how it is to be used. The Department of Health, Education, and Welfare regards the supplying of printed matter to the pharmacist for his professional information, and not as a means of over-the-counter sales promotion, such as by display to prospective purchasers, as a legitimate means of making information necessary for professional use readily available. This Department has no intention of recommending action based on the supplying or use of such material for that professional purpose.

§ 3.14 *Notice to manufacturers and distributors of foods and drugs containing artificial sweeteners.* Chronic-toxicity studies conducted by the Department of Health, Education, and Welfare show that the artificial sweeteners dulcin (also known as sucrol, or 4-ethoxyphenylurea, or paraphenetolcarbamide) and P-4000 (also known as 1-n-propoxy-2-amino-4-nitrobenzene) cause injury to rats when fed at relatively low levels for approximately 2 years. Consequently, the Secretary of Health, Education, and Welfare regards these chemicals as poisonous substances which have no place in any food.

Pending further evaluation of available data, it is not possible to state the conditions under which dulcin or P-4000 would render a drug in which it is used dangerous to health. Since other artificial sweeteners are available which have a much greater margin of safety in chronic-toxicity studies, the use of dulcin and P-4000 as sweeteners of drugs is to be discouraged.

§ 3.15 *Notice to manufacturers and labelers of antibiotic and antibiotic-containing drugs.* Recent investigations by the Department of Health, Education, and Welfare have revealed that a number of persons engaged in manufacturing and selling antibiotic and antibiotic-containing drugs are introducing into interstate commerce shipments of these drugs that are unlabeled, or not fully labeled, and are not exempt from labeling under the provisions of § 146.18 of this chapter. This practice has been based upon the belief that interstate shipments of antibiotic and antibiotic-containing drugs to persons engaged in the export trade are not subject to certification.

When these drugs are introduced into interstate commerce they must be certified, exempted from labeling under § 146.18, of this chapter, or exempted from misbranding by meeting all the conditions specified in section 801 (d) of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 381 (d)). Section 801 (d) of the act is not satisfied merely by shipment of drugs to exporters. If exemption under this section is to be claimed, the drugs, at the time of introduction into interstate commerce, must be marked for export, must accord to the specifications of the foreign purchaser, and must not be in conflict with the laws of the country to which they are intended for export. The initial shipper has a responsibility to meet all the conditions of section 801 (d) if exemption is to be claimed. It is not enough that he is shipping to a person engaged in the export trade who will obtain a foreign purchaser, who will mark the goods for export, and who will obtain assurance that the drug is not in conflict with the laws of the country to which it is intended for export.

Section 146.18 of this chapter provides exemption from labeling. If the original shipper has an effective exemption permit under the regulations in Part 146, the exporting firm named in the exemption permit may be allowed to receive and to hold the unlabeled drugs under the exemption until the conditions of section 801 (d) of the act are satisfied.

§ 3.16 *Notice to manufacturers, packers, and distributors of drug products.* Conferences have recently been held between members of the Department of Health, Education, and Welfare and representatives of the Agricultural Research Service, Department of Agriculture, concerning requests made to that agency for the release of ox bile from condemned livers of slaughtered animals for use in the manufacture of certain drugs.

The Secretary of Health, Education, and Welfare has given careful consideration to this problem and has reached the conclusion that no hazard to public health will be involved in the release of such ox bile, after the addition to it of sufficient sodium hydroxide to give the mixture a sodium hydroxide content of not less than 5 percent, the mixture then being allowed to stand at least 24 hours. This Department will not regard as in violation of the provisions of the Federal Food, Drug, and Cosmetic Act such alkalized and aged ox bile, if labeled "Ox Bile and Sodium Hydroxide (or Ox Bile and Sodium Hydroxide Solution). Sodium hydroxide not less than 5 percent by weight. For manufacturing use only," together with a statement of the quantity of contents in the container (for example, "50 gallons") and the name and address of the manufacturer, packer, or shipper.

Bile from the condemned livers of sheep and goats also may be released, under the same conditions as outlined in the preceding paragraph, except that the words "Sheep Bile" or "Goat Bile," as the case may be, shall be substituted for the words "Ox Bile" upon the label. In the case of mixtures of bile from any two or all three of the sources mentioned, the label shall indicate the sources of such bile.

§ 3.17 *Labeling of oleomargarine.* The Federal Food, Drug, and Cosmetic Act was amended by the recently enacted legislation (64 Stat. 20) on colored oleomargarine. A new section numbered 407 was added. Among other things, the new section requires that there appear on the label of the package the word "oleomargarine" or "margarine" in type or lettering at least as large as any other type or lettering on such label, and a full and accurate statement of all the ingredients contained in such oleomargine or margarine. It provides that these requirements "shall be in addition to and not in lieu of any of the other requirements of this Act."

(a) Under section 403 (g) of the Federal Food, Drug, and Cosmetic Act any article that is represented as or purports to be oleomargarine must conform to the definition and standard of identity for oleomargarine promulgated under section 401 of the act (Part 45 of this chapter), and its label must bear the name "oleomargarine," which is the name specified in the standard. It is this Department's view that the name "oleomargarine" should appear on the label, until the standard is amended.

(b) While under the provisions of the identity standard for oleomargarine only certain of the optional ingredients authorized by the standard are required to be declared on the label, section 407 requires, in the case of colored oleomargarine, "a full and accurate statement of all the ingredients contained in such oleomargarine or margarine." The following optional ingredients authorized by the identity standard for oleomargarine and the names by which we believe such ingredients, when present, should be declared in order to constitute "a full and accurate statement" are set forth below:

(1) The rendered fat, or oil, or stearin derived therefrom (any or all of which may be hydrogenated), of cattle, sheep, swine, or goats, or any combination of two or more of such articles—to be declared by the name of the specific animal fat, oil, or stearin, for example, "beef fat."

(2) Any vegetable food fat or oil, or oil or stearin derived therefrom (any or all of which may be hydrogenated), or any combination of two or more of such articles—to be declared as, for example, "cottonseed oil" or "soybean oil," or if such oils are present in the same batch or lot, as "cottonseed oil, soybean oil, peanut oil, and corn oil," listing the predominating oils of the mixture ahead of those which are present in much smaller quantities. If the oil or oils present are hydrogenated, the declaration should be, for example, "hydrogenated cottonseed oil" or "hardened cottonseed oil."

(3) The optional ingredients cream, milk, skim milk, or dried skim milk (nonfat dry milk solids or defatted milk solids) and water, butter, and salt should be declared by those terms.

(4) Artificial color and artificial flavor should be declared as such by the terms prescribed in the identity standard for oleomargarine. They need not be additionally declared by the names of the specific colors or flavors.

(5) The presence of sodium benzoate or benzoic acid should be declared as prescribed by the identity standard for oleomargarine.

(6) The optional ingredient vitamin A added in an essential carrier may be declared merely as "vitamin A added" or "with added vitamin A."

(7) The optional ingredient vitamin D may be declared as "vitamin D added" or "with added vitamin D."

(8) The optional emulsifying ingredients lecithin, mono- or diglycerides and sodium sulfo-acetate derivatives of mono- or diglycerides should be declared by those terms.

(9) The statement of all the ingredients contained in colored oleomargarine is subject to the requirements pertaining to conspicuousness in section 403 (f) of the act.

(c) In considering the requirement that the word "oleomargarine" be in type or lettering at least as large as any other type or lettering on the label, it must be borne in mind that other factors than mere height of lettering are involved. The type or lettering of the word "oleomargarine" should be compared with other type or lettering from the standpoint of:

(1) The area occupied by each letter as measured by a closely fitting rectangle drawn around it. The area of such rectangle with respect to any of the letters in the word "oleomargarine" should equal or exceed the area of such rectangle applied to the same or a corresponding letter elsewhere on the label. A single letter may be the largest type on the label, in which case each letter in the word "oleomargarine" must be at least as large as that letter.

(2) The boldness of letters, or breadth of the lines forming the letters which constitute factors in determining largeness. The letters in the word "oleomargarine" should equal or exceed in boldness and prominence that of the same or corresponding letters elsewhere on the label.

(d) Colored oleomargarine containing the optional ingredients vitamin A and/or vitamin D continues to be subject to the labeling requirements of section 403 (j) of the act pertaining to foods for special dietary use.

(e) The word "oleomargarine" (and thus the other information called for by the statute) should appear on each panel of the package label which might reasonably be selected by the grocer for display purposes at the point of sale.

(f) The colored-oleomargarine amendment states that "for the purposes of this section [section 15 of the Federal Trade Commission Act, as amended] and section 407 of the Federal Food, Drug, and Cosmetic Act, as amended, the term 'oleomargarine' or 'margarine' includes (1) all substances, mixtures, and compounds known as oleomargarine or margarine; (2) all substances, mixtures, and compounds which have a consistence similar to that of butter and which contain any edible oils or fats other than milk fat if made in imitation or semblance of butter." Notwithstanding the difference between this definition and the definition and standard of identity for oleomargarine promulgated under section 401 of the act, it was the clear intent of Congress that any article which is represented as or purports to be oleomargarine and which fails to comply with the definition and standard of identity for oleomargarine is misbranded under section 403 (g), even though it may meet the new statutory definition. This ban on an article which fails to comply with the definition and standard of identity for oleomargarine heretofore has not applied to colored or uncolored oleomargarine sold within the same State in which manufactured. By the terms of the new section 407 colored oleomargarine or colored margarine which is sold in the same State or Territory in which it is produced is subject in the same manner and to the same extent to the provisions of this act as if it had been introduced into interstate commerce.

(g) Section 407 (b) (4) requires that each part of the contents of the package be "contained in a wrapper which bears the word 'oleomargarine' or 'margarine' in type or lettering not smaller than 20-point type." We interpret this to mean that the height of the actual letters is not less than 20 points, or $\frac{20}{72}$ of 1 inch.

(h) Since wrapped quarter-pound sticks of oleomargarine may constitute units of retail sale, they should be individually labeled with all the mandatory label information required by sections 403 and 407 of the Food, Drug, and Cosmetic Act, just as in the case of 1-pound cartons.

§ 3.19 *Notice to manufacturers, packers, and distributors of pasteurized process cheese, pasteurized blended cheese, pasteurized process cheese food, pasteurized process cheese spread, and related foods.* (a) Definitions and standards of identity have recently been promulgated under the authority of the Federal Food, Drug, and Cosmetic Act for a number of foods made in part from cheese, including pasteurized process cheese; pasteurized process cheese with fruits, vegetables, or meats; pasteurized blended cheese; pasteurized process cheese food; pasteurized process cheese spread, and related foods. These standards prescribe the name for each such food. The act requires that this name appear on the label. Many of these names consist of several words. In the past it has been the practice of some manufacturers to subordinate the words "pasteurized," "blended," "process," "food," and "spread" to give undue prominence to the word "cheese" and to words naming the variety of cheese involved.

(b) When placing the names of these foods on labels so as to comply with the requirements of section 403 (a), (f), and (g) of the act, all the words forming the name specified by a definition and standard of identity should be given equal prominence. This can readily be accomplished by printing the specified name of the food in letters of the same size, color, and style of type, and with the same background.

(c) Where the names of optional ingredients are required to appear on the label, the designations of all such ingredients should be given equal prominence. The names of the optional ingredients should appear prominently and conspicuously but should not be displayed with greater prominence than the name of the food. The word "contains" may precede the names of the optional ingredients, and when so used will not be considered as intervening printed matter between name of food and name of optional ingredients required to be placed on the label.

(d) Where a manufacturer elects to include a label statement of fat and moisture content, the declaration should be on the basis of the food as marketed. A fat declaration on a moisture-free basis is likely to be misleading, and should not be used in labeling.

§ 3.20 *Status of salt substitutes under the Federal Food, Drug, and Cosmetic Act.* Under date of March 8, 1949, the Department of Health, Education, and Welfare announced (§ 3.9) that it would regard each salt substitute as a new drug within the meaning of section 201 (p) of the Federal Food, Drug, and Cosmetic Act, and that interstate distribution of each salt substitute should be discontinued until a new-drug application had been filed and become effective. Substantial information concerning the safety of many of the ingredients used in salt substitutes has been developed and published since the announcement was made. It is now possible to evaluate the safety of many individual salt substitutes and to determine whether they are new drugs requiring effective applications prior to distribution in interstate commerce.

The Department of Health, Education, and Welfare therefore no longer regards all salt substitutes as new drugs. Upon request, the Department will express its opinion as to whether a new-drug application is necessary for any particular product if complete information concerning its composition and proposed labeling is submitted.

§ 3.21 *Notice to manufacturers of pasteurized process cheese food and pasteurized process cheese spread.* Regulations establishing definitions and standards of identity for pasteurized process cheese food and pasteurized process cheese spread appear in §§ 19.765 and 19.775 of this chapter, respectively. These regulations became effective on February 24, 1951.

An application has been received from a substantial portion of the interested industry proposing to amend these regulations to permit skim milk cheese for manufacturing as an optional ingredient in these foods. Alternative ways of amending the regulations are suggested: (1) To permit skim milk cheese for manufacturing as an optional cheese ingredient under paragraph (c) of each of the sections; or (2) To permit skim milk cheese for manufacturing as an optional dairy ingredient under paragraph (d) of each of the sections.

A hearing to take evidence on these proposals will be called as soon as practicable. Pending such a hearing and the issuance of an order resulting therefrom, the Department of Health, Education, and Welfare will not recommend action against pasteurized process cheese foods or pasteurized process cheese spreads solely because they include skim milk cheese for manufacturing as part of the optional cheese or dairy ingredients. Such foods must comply with other requirements of the existing regulations as well as the general provisions of the law.

§ 3.22 *Suprarenal glands from hog carcasses prior to final inspection.* The Agricultural Research Service of the U. S. Department of Agriculture has informed the Food and Drug Administration of the Department of Health, Education, and Welfare that, under appropriate conditions, it will permit the removal of suprarenal glands from hogs that have not been finally inspected by Federal inspectors. The glands to be so obtained are intended for use in manufacturing extracts containing one or more of the therapeutically useful constitutents of suprarenal glands.

Under the conditions specified in this section, the Secretary of Health, Education, and Welfare has determined that the public health will be adequately protected from any danger from the use of drugs, made in whole or in part from suprarenal glands of hogs that may be condemned by Federal inspectors of the Department of Agriculture after removal of such glands from the carcasses, arising from any abnormality of such carcasses if such glands are subjected to the following prescribed treatment, which will destroy or eliminate any microorganisms or toxins that might be present in the glands:

The glands are subjected to quick freezing promptly upon removal from the carcasses and maintained in a frozen state until they are ground and immersed in 95 percent to 100 percent acetone. The ground tissues remain in the acetone for a period of not less than 6 days, the mixture is filtered, and the residue is burned.

§ 3.23 *Notice to manufacturers and users of monosodium glutamate and other hydrolyzed vegetable protein products.* Following a review of various statements submitted by manufacturers and distributors of monosodium glutamate and various hydrolyzed plant protein products, the following conclusions have been reached:

(a) The facts submitted establish that there are three classes of products to be considered:

(1) Purified monosodium glutamate.

(2) Hydrolyzed proteins (amino acid salts) from which none of the monosodium glutamate has been removed.

(3) Hydrolyzed proteins (amino acid salts), a by-product in the manufacture of purified monosodium glutamate but from which a substantial proportion of the monosodium glutamate has been removed.

(b) The statement of policy appearing in § 3.10 is reaffirmed. Monosodium glutamate is the common or usual name of the substance covered in said statement of policy. It need not be declared as an artificial flavoring, but when used as an ingredient of food products should be declared by its common or usual name. It may not be used in a food for which a standard of identity has been promulgated unless the standard or any amendment thereto recognizes it as an optional ingredient. It may not be used under any circumstances in such a way as to conceal damage or inferiority or make the article appear better or of greater value than it is.

(c) (1) The substance described in paragraph (a) (2) of this section has long been designated as "hydrolyzed vegetable protein."

(2) The substance covered by paragraph (a) (3) of this section should have a distinctive name, since one of its original constituents has been partially removed. Manufacturers have suggested that this substance be described as "hydrolyzed vegetable protein with reduced monosodium glutamate content." This designation appears acceptable.

(d) While the substances referred to in paragraph (a) (2) and (3) of this section contain a number of amino acid salts as well as sodium chloride, monosodium glutamate is the ingredient which has been quite generally emphasized, and is best known to consumers under that name. No objection is offered under the Federal Food, Drug, and Cosmetic Act to the addition of a quantitative declaration on the labels of containers of such hydrolyzed vegetable protein or hydrolyzed vegetable protein with reduced monosodium glutamate content showing the percentage amounts of monosodium glutamate, the total of other amino acid salts, salt, and water, if in liquid form, all to be declared in the order of their decreasing percentages. If monosodium glutamate represents a smaller proportion of the substance than the other amino acid salts and salt (sodium chloride), it should be declared last in the list of ingredients.

(e) When the substances described in paragraphs (a) (2) and (3) of this section are used as ingredients in a fabricated food, either may be declared as "salt and hydrolyzed vegetable protein" (or "salt and hydrolyzed plant protein") on the label of the fabricated food product; *Provided,* That where salt is declared as a separate ingredient of the fabricated food, in compliance with section 403 (i) (2) of the act, the word "salt" need not be repeated in connection with the "hydrolyzed vegetable protein" (or "hydrolyzed plant protein") declaration.

§ 3.24 *Notice to packers of comminuted tomato products.* It has long been known that tomato rot may be caused by one or more of the following: Fungus diseases, bacterial diseases, virus diseases, and certain nonparasitic diseases. Only the fungus rots are characterized by the presence of mold filaments. Mold counts on comminuted tomato products are not increased by incorporating within the product tomato rot caused by bacteria, virus, or nonparasitic factors. Although high mold counts on these products reveal that large amounts of rotten material are present, low mold counts do not necessarily demonstrate absence of the type of rot caused by the tomato diseases that are not characterized by mold filaments.

Inspections of canneries engaged in the packing of comminuted tomato products show that most packers effectively trim, sort out, and discard rotten tomatoes from the raw stock. Some packers, however, do not properly eliminate rotten tomato material, and a few packers deliberately use rotten tomatoes in these foods, provided the mold count remains low. Some packers, on occasion, have mixed tomato products having a high mold count with tomato products containing little or no mold, so as to produce a blend with a low mold count.

Packers of comminuted tomato products who rely upon the mold count as the sole or primary control procedure, to the neglect of adequate sorting and trimming, may produce products with low mold counts which contain substantial amounts of rot.

It is the purpose of this announcement to advise all canners of tomato products that:

(a) Although high mold count is conclusive evidence of inclusion of substantial amounts of rot, mold count is not the only way of establishing that comminuted tomato products contain decomposed tomato material.

(b) Where factory observations or other evidence reveals that comminuted tomato products contain rot not caused by mold, such rot, as well as that caused by mold, will be taken into account in applying the provisions of the Federal Food, Drug, and Cosmetic Act against adulteration.

(c) The blending of tomato products adulterated with tomato rot, of whatever kind, with tomato products made from sound tomatoes, or with other sound food, renders the blend adulterated.

§ 3.25 *Notice to manufacturers and labelers of antibiotic drugs for veterinary use.* Unless a proper interval of time is allowed following the use of antibiotic drugs for the treatment of mastitis in milk-producing animals, the antibiotic drugs may get into the general milk supply. Because of the specific action of antibiotic drugs on cheese starters, milk containing such drugs is of no value to cheese manufacturers.

The direct or inadvertent addition of antibiotic drugs to milk to be sold for human consumption or for the manufacture of dairy products may constitute an adulteration within the meaning of section 402 of the Federal Food, Drug, and Cosmetic Act (sec. 402, 52 Stat. 1046; 21 U. S. C. 342).

The labeling of antibiotic drugs intended for intramammary use in the treatment of mastitis in milk-producing animals should bear a prominent statement designed to prevent milk from treated portions of the udder from entering the general milk supply. The following statement is recommended for this purpose: "*Important:* Milk from treated segments of udders should be discarded or used for purposes other than human consumption for at least 72 hours after the last treatment."

§ 3.26 *Labeling exemptions for foods repackaged in retail food establishments.* The Secretary of Health, Education, and Welfare will refrain from recommending criminal, injunction, or seizure proceedings on charges that a food repackaged in a retail establishment was misbranded, while held for sale, because it did not comply with the following provisions of the Federal Food, Drug, and Cosmetic Act, if the conditions herein specified are met:

(a) Section 403 (e) (1) (requiring a statement on the label of the name and place of business of the manufacturer, packer, or distributor);

(b) Section 403 (g) (2) (requiring the label of a food which purports to be or is represented as one for which a definition and standard of identity has been prescribed to bear the name of the food specified in the definition and standard and, insofar as may be required by the regulation establishing the standard, the common names of the optional ingredients present in the food), if the food was displayed to the purchaser with its interstate labeling clearly in view, or with a counter card, sign, or other appropriate device bearing prominently and conspicuously the information required by these provisions; or

(c) Section 403 (i) (1) (requiring the label to bear the common or usual name of the food), if the food was displayed to the purchaser with its interstate labeling clearly in view, or with a counter card, sign, or other appropriate device bearing prominently and conspicuously the common or usual name of the food, or if the common or usual name of the food is clearly revealed by its appearance.

§ 3.27 *Status of fluoridated water and foods prepared with fluoridated water under the Federal Food, Drug, and Cosmetic Act.* (a) The program for fluoridation of public water supplies recommended by the Department of Health, Education, and Welfare, through the Public Health Service, contemplates the controlled addition of fluorine at a level optimum for the prevention of dental caries.

(b) Public water supplies do not ordinarily come under the provisions of the Federal Food, Drug, and Cosmetic Act. Nevertheless, a substantial number of inquiries have been received concerning the status of such water under the provisions of the act and the status, in interstate commerce, of commercially prepared foods in which fluoridated water has been used.

(c) The Department of Health, Education, and Welfare will regard water supplies containing fluorine, within the limitations recommended by the Public Health Service, as not actionable under the Federal Food, Drug, and Cosmetic Act. Similarly, commercially prepared foods within the jurisdiction of the act, in which a fluoridated water supply has been used in the processing operation, will not be regarded as actionable under the Federal law because of the flourine content of the water so used, unless the process involves a significant concentration of fluorine from the water. In the latter instance the facts with respect to the particular case will be controlling.

§ 3.28 *Notice to manufacturers and repackers of ophthalmic solutions.* (a) Investigations by pharmaceutical manufacturers, physicians, and the Food and Drug Administration have revealed that liquid preparations for ophthalmic use contaminated with viable microorganisms have been responsible for serious eye injuries and, in some cases, complete loss of vision. The Food and Drug Administration has conducted a survey of medical opinion and has found that it is the consensus of informed persons that such preparations should be sterile. It is evident that liquid preparations offered or intended for ophthalmic use purport to be of such purity and quality as to be suitable for safe use in the eye. The Department of Health, Education, and Welfare concludes that such preparations fall below their professed standard of purity or quality and may be unsafe for use if they are not sterile. Accordingly, liquid preparations offered or intended for ophthalmic use which are not sterile may be regarded as adulterated within the meaning of section 501 (c) of the Federal Food, Drug, and Cosmetic Act and, further, may be misbranded within the meaning of section 502 (j) of the act.

(b) Liquid ophthalmic preparations packed in multiple-dose containers should (1) contain one or more suitable and harmless substances that will prevent the growth of micro-organisms, or should (2) be so packaged as to volume and type of container and so labeled as to duration of use and necessary warnings as will afford adequate protection and minimize the hazard of injury resulting from contamination during use.

§ 3.29 *Direct or indirect addition of antibiotic drugs to foods for human consumption.* (a) The Food and Drug Administration has received inquiries concerning the use of antibiotic drugs as food preservatives. Careful consideration has been given to this question and the conclusion has been reached that such use constitutes a public-health hazard. Consumption of food so treated may cause sensitization of the consumer to such antibiotics and may result in the emergence of strains of pathogenic micro-organisms resistant to these drugs.

(b) The presence of antibiotic drugs in foods intended for human consumption, or the direct or indirect addition of such drugs to such foods, may be deemed an adulteration within the meaning of section 402 of the Federal Food, Drug, and Cosmetic Act (sec. 402, 52 Stat. 1046; 21 U. S. C. 342).

(c) This statement of policy will not bar the establishment of safe tolerances for antibiotic drugs in or on raw agricultural commodities under the provisions of section 408 of the act, where suitable evidence of usefulness of the antibiotic drugs and of safety of the residue is available.

§ 3.30 *Shipment of antibiotic drugs packaged in bulk containers.* (a) The Food and Drug Administration has received inquiries from certain interested manufacturers concerning their shipment of certified antibiotics, packaged in bulk containers, to hospitals and pharmacies for repacking or for use in the manufacture of another drug on the order or prescription of a physician. The regulations promulgated under section 507 of the Federal Food, Drug, and Cosmetic Act (21 U. S. C. 357) do not prohibit the shipment of certified bulk containers of antibiotics to such persons. However, under the provisions of § 146.4 (b) (2) (i) of this chapter, certification should be requested of each repacked batch and of each batch of another drug manufactured from such bulk drug, unless the repackaged drug or other drug has been made exempt from the certification requirements by regulation. The fact that the drug is to be repacked or manufactured on the order or prescription of a physician does not exempt it from the certification requirements of the act. Under the provisions of § 146.4 (b) (2) (ii) of this chapter, it is only when the drug used to compound a prescription is in a container packaged for dispensing that certification of the drug so compounded is not required.

(b) In the light of these provisions, unless the manufacturer and shipper of bulk containers of antibiotics has, with the consignee, an effective permit issued under § 146.21 of this chapter, if the drug is to be repacked, or under § 146.22 of this chapter if it is to be used in the manufacture of another drug, the shipper has the responsibility of seeing that certification is requested of each repacked batch and of each batch of another drug manufactured from such drug.

§ 3.31 *Label declaration of salt in frozen vegetables.* (a) In a number of diseases or disease conditions it is important to restrict the intake of sodium. Sodium occurs in all natural foods, but added salt makes the most important contribution to the total sodium intake in the diet. Most fresh vegetables are of low sodium content and consumers generally regard frozen vegetables as being free of added salt and suitable for use in low-sodium diets. While salt may not be added directly as a seasoning ingredient during the processing of frozen vegetables, the use of salt brine in quality separation of such vegetables as peas and lima beans preparatory to freezing may contribute substantial amounts of salt to the finished article. The failure of the labels of frozen vegetables to declare the presence of salt has been the basis of complaints to the Food and Drug Administration.

(b) Section 403 (i) (2) of the Federal Food, Drug, and Cosmetic Act requires the label of a fabricated food to bear the common or usual name of each ingredient present. The Department of Health, Education, and Welfare regards any frozen vegetable containing salt, added directly or indirectly, as misbranded in violation of section 403 (i) (2) of the Federal Food, Drug, and Cosmetic Act unless its label names salt as an ingredient.

§ 3.32 *Label declarations of vitamin B_{12}, and folic acid in foods for special dietary uses.* (a) Section 125.3 (a) (2) of this chapter, issued under the authority of section 403 (j) of the Federal Food, Drug, and Cosmetic Act (sec. 403 (j), 52 Stat. 1048; 21 U. S. C. 343 (j)) requires that if a food purports to be or is represented for special dietary use by man by reason, in whole or in part, of a vitamin for which the need in human nutrition has not been established, the label of such food shall bear the statement "The need for ______ in human nutrition has not been established," the blank to be filled in with the name of such vitamin.

(b) Heretofore this Department has considered vitamin B_{12} and folic acid as among those vitamins for which the need in human nutrition has not been established. However, recent scientific evidence shows that these vitamins are needed in human nutrition. The Department therefore considers the requirement of § 125.3 (a) (2) quoted in paragraph (a) of this section as no longer applicable to food offered for special dietary use by reason of these vitamins.

(Sec. 403, 52 Stat. 1048; 21 U. S. C. 343)

§ 3.33 *Status of foods containing added coumarin.* Manufacturers of coumarin have reported pharmacological investigations showing that it has toxic properties. They have informed the Food and Drug Administration that it will no longer be sold for food use. The Federal Food, Drug, and Cosmetic Act defines food as adulterated if it contains any added poisonous or deleterious substance not required in the production or avoidable in good manufacturing practice. Food containing coumarin added as such or as a constituent of tonka beans or tonka extract will be regarded as adulterated under this provision of the law.

(Secs. 402, 406, 52 Stat. 1046, 1049; 21 U. S. C. 342, 346)

§ 3.34 *Labeling of imported crabmeat.* (a) For many years canned crabmeat has been imported into the United States from Japan. Such imports have consisted primarily of a product designated as "King crabmeat." There have been limited importations of articles designated as "Korean crabmeat" and "Snow crabmeat." Two closely allied species of crab have been packed in Japan for export to the United States, under the designation "King crabmeat." These species are Paralithodes camtschatica (taraba-gani) and Paralithodes platypus (abura-gani). A third species of crab, Paralithodes brevipes, has been labeled either as "King crabmeat" or "Hanasaki crabmeat" when intended for export to the United States. The Department of Health, Education, and Welfare considers the term "King crabmeat" as an acceptable common name for the product prepared from any one of the three species Paralithodes camtschatica, Paralithodes platypus, and Paralithodes brevipes. The Department also considers the name "Hanasaki crabmeat" as an alternative common name for the product prepared from Paralithodes brevipes.

(b) Prior to World War II, there was a limited pack of crabmeat from the species Erimacrus isenbeckii at canneries located on the coast of Korea, but only a small quantity of this product was imported into the United States. To distinguish the product from the various species of Paralithodes and to connote its geographic origin, the article was designated by the name "Korean crab." For the past several years there has been a limited amount of the species Erimacrus isenbeckii packed in Japan or on Japanese factory ships operating in the Bering Sea. This species of crab is generally known in Japan as "Kegani." This product, packed in Japan, when offered for entry into the United States has been designated by a variety of names, including "Korean crabmeat," "Snow crabmeat," "Eliza crabmeat," "Kegani crabmeat," and "Zuwai crabmeat," with resulting confusion to importers and consumers. The term "Korean crab" is no longer applicable to the product as an indication of its geographic origin. The long absence of the product from the domestic market, until its recent reintroduction under a variety of names, has largely eliminated consumer recognition of the identity of the product under the name "Korean crabmeat." The Department therefore considers the designation "Korean variety crabmeat" or, alternatively, "Kegani crabmeat" as suitable common names for the product packed from the species Erimacrus isenbeckii.

(c) There has also been a limited pack of Chionectes opilio (zuwai-gani) offered for entry into the United States. This product has for many years been designated by the name "Snow crabmeat." The Department regards the designation "Snow crabmeat" as the common or usual name for the product when distributed in the United States.

(d) Section 403 (i) (1) of the Federal Food, Drug, and Cosmetic Act requires that the label of a food for which there is no definition and standard of identity shall bear the common or usual name of the food, if any there be. No definition and standard of identity has been established for crabmeat under the act. The Department of Health, Education, and Welfare regards the label designations for canned crabmeat prepared from the various species of crab as stated in paragraphs (a), (b), and (c) of this section as satisfactory compliance with section 403 (i) (1) of the act.

(Sec. 403, 52 Stat. 1048; 21 U. S. C. 343)

§ 3.35 *Labeling of drug preparations containing significant proportions of wintergreen oil.* (a) Because methyl salicylate (wintergreen oil) manifests no toxicity in the minute amounts in which it is used as a flavoring, it is mistakenly regarded by the public as harmless even when taken in substantially larger amounts. Actually, it is quite toxic when taken in quantities of a teaspoonful or more. Wintergreen oil and preparations containing it have caused a number of deaths through accidental misuse by both adults and children. Children are particularly attracted by the odor and are likely to swallow these products when left within reach.

(b) To safeguard against fatalities from this cause, the Department of Health, Education, and Welfare will regard as misbranded under the provisions of the Federal Food, Drug, and Cosmetic Act any drug containing more than 5 percent methyl salicylate (wintergreen oil), the labeling of which fails to warn that use otherwise than as directed therein may be dangerous and that the article should be kept out of reach of children to prevent accidental poisoning.

(c) This statement of interpretation in no way exempts methyl salicylate (wintergreen oil) or its preparations from complying in all other respects with the requirements of the Federal Food, Drug, and Cosmetic Act.

(Sec. 502, 52 Stat. 1051; 21 U. S. C. 352)

§ 3.36 *Procedure for establishing food standards under the Federal Food, Drug, and Cosmetic Act.* The procedure prescribed in the Federal Food, Drug, and Cosmetic Act for the issuance, amendment, or repeal of standards for foods has recently been modified by Congress. The new amendment permits any interested person showing reasonable grounds therefor to petition the Secretary of Health, Education, and Welfare to initiate action.

(a) If the petitioner shows that he is an interested person and furnishes reasonable grounds for his proposal, it is the duty of the Secretary to publish the proposal and afford opportunity for other interested persons to comment on it. After a study of all the facts available and of the comments received, the Secretary will act upon the proposal and publish an order, to which objection may be taken by persons who would be adversely affected. Thus the issues in controversy are singled out for a public hearing.

(b) Practical administration of the law requires that there be a substantial showing of merit before any proposal is published. In passing on proposals submitted by petitioners for initiating actions, it will be the policy of the Department of Health, Education, and Welfare to consider that reasonable grounds have been furnished when:

(1) The proposal includes or is accompanied by a statement of the facts that the petitioner asserts he is in a position to substantiate by evidence in the event the proceedings lead to a public hearing.

(2) The facts declared furnish substantial support of the proposal and warrant a conclusion that the proposal is reasonable.

(3) The proposal, if adopted, would promote honesty and fair dealing in the interest of consumers.

(c) Opportunity will be given to amend petitions regarded as inadequate.

(Sec. 401, 52 Stat. 1046, as amended, 68 Stat. 54; 21 U. S. C. 341)

§ 3.37 *Confidentiality of information contained in new-drug applications.* (a) The Federal Food, Drug, and Cosmetic Act provides, in section 505 (b), that any person may file with the Secretary of Health, Education, and Welfare an application with respect to any new drug, which shall include, among other things, a full list of the articles used as components and a full statement of the composition of such drug. These requirements apply to all components or ingredients of a new drug, whether or not they are therapeutically active. Fulfillment of these requirements may be met by submitting a full statement of the chemical or common or usual name and of the quantity of each component or ingredient of the drug. Such requirements may also be met through the inclusion in the new-drug application of a properly authorized reference to a previous application or other Food and Drug Administration file containing the relevent information.

(b) The Food and Drug Administration treats information in new-drug applications as confidential. Section 301 (j) of the Federal Food, Drug, and Cosmetic Act makes it an offense to divulge to unauthorized persons any information acquired from a new-drug application concerning any method or process that is a trade secret. Basic manufacturers sometimes submit data to the Food and Drug Administration in the form of so-called master files for the purpose of establishing the safety of ingredients that may be used in new drugs and authorize specified applicants to refer to the data in support of their own new-drug applications. Such manufacturers may regard some of the data in such files as trade secrets and request the Food and Drug Administration to treat such information as confidential. The Food and Drug Administration will preserve the confidentiality of such data to the extent that it may properly do so. Because the applicant is legally responsible for the composition of the new drug and all its ingredients and may require information in the master file for judicial or administrative proceedings concerning the drug, the Food and Drug Administration will not withhold such information from the applicant when his need for it arises and he submits a written request for it.

(Secs. 301, 505, 52 Stat. 1042, 1052; 21 U. S. C. 331, 355)

§ 3.38 *Declaration of quantity of contents on labels for canned oysters.* (a) For many years packers of canned oysters in the Gulf area of the United States have labeled their output with a declaration of the drained weight of oysters in the containers. Packers in other areas have marketed canned oysters with a declaration of the total weight of the contents of the container. Investigation reveals that under present-day practice consumers generally do not discard the liquid packing medium, but use it as a part of the food. Section 403 (e) (2) of the Federal Food, Drug, and Cosmetic Act and the regulations thereunder require food in package form to bear an accurate label statement of the quantity of food in the container.

(b) It is concluded that compliance with the label declaration of quantity of contents requirement will be met by an accurate declaration of the total weight of the contents of the can. The requirements of § 36.6 of this chapter, establishing a standard of fill of container for canned oysters and specifying the statement of substandard fill for those canned oysters failing to meet that standard remain unaffected by this interpretation.

(Sec. 403, 52 Stat. 1047; 21 U. S. C. 343)

§ 3.39 *Use of vegetable fat in products which are imitations of ice cream.* There is currently being marketed in interstate commerce a frozen product made in semblance of ice cream, but containing vegetable fats in complete or partial substitution for milk fat. In some cases the product is marketed under a fanciful designation. Such a product is now regarded as an imitation of ice cream, and thus amenable to the provision of the Federal Food, Drug, and Cosmetic Act requiring the label to bear the name "Imitation Ice Cream," with all these words in type of uniform size and prominence, regardless of whether a fanciful designation is used.

(Secs. 402, 403; 52 Stat. 1047; 21 U. S. C. 342, 343)

§ 3.40 *Pesticide chemicals; date on which statute becomes fully effective.* (a) The pesticide chemicals amendment to the Federal Food, Drug, and Cosmetic Act (68 Stat. 511) is scheduled to become fully effective on July 22, 1955. However, the Secretary of Health, Education, and Welfare may extend this date on a product-by-product basis for a time not to exceed 12 months on a finding that conditions exist that necessitate the extension of such additional period. After the amendment becomes fully effective, a raw agricultural commodity in interstate commerce may bear residues of a poisonous pesticide chemical only if:

(1) Under the provisions of the Federal Food, Drug, and Cosmetic Act a tolerance has been established for residues of the pesticide chemical, or it has been exempted from the requirement of a tolerance; and

(2) If a tolerance has been established, the residues are within the tolerance level.

Numerous tolerances for residues of pesticide chemicals—and some exemptions from the requirement of a tolerance—have been established. However, tolerances or exemptions have not been established for some pesticide chemicals that are employed in agriculture, and it is not possible at this time to determine whether tolerances will be established for them before the end of the current growing season. Some of these pesticides have been recommended by certain State officials for use on crops throughout the 1955 growing season. Agriculturists, pesticide manufacturers and distributors, and food-law enforcement officials need to know the status of these pesticides under the amendment prior to July 22, 1955, so that they will know whether the pesticides should be employed throughout the 1955 growing season.

(b) The Department of Health, Education, and Welfare is prepared to consider requests for an extension of the effective date of the law for specific pesticides. The following criteria, among others, will be used in evaluating and acting upon such requests:

(1) There should not be an extension of the effective date of the amendment for uses of pesticide chemicals for which tolerances have already been established.

(2) The effective date of the amendment should be extended for a pesticide

chemical only upon a finding, based on a study of the available facts about the chemical and its toxicity, that the interests of public health will not be jeopardized by the extension.

(3) There should be evidence about the amounts of residues which remain in or on food from use of a pesticide chemical and about its chronic toxicity before an extension is granted.

(4) Extension should not be granted for a pesticide chemical which causes alarming symptoms in test animals (cancer or blood disorders, for example) in any dosage, unless experimental data show a level of feeding to test animals that is safe.

(5) Where a tolerance has been set for residues of a pesticide chemical on one or more raw agricultural commodities under the Federal Food, Drug, and Cosmetic Act, and the other criteria of this statement of policy are met, the effective date may be extended for other uses of the pesticide chemical.

(6) Extension should be granted only for uses of a pesticide chemical registered with the Department of Agriculture under the Federal Insecticide, Fungicide, and Rodenticide Act of 1947 (61 Stat. 163; 7 U. S. C. 135) prior to the 1955 growing season (prior to May 1, 1955).

(7) Extension should be granted only to the end of the 1955 growing season, because longer extensions would result in confusion during the 1956 growing season. The principal growing season in the United States ends by October 31.

(8) Notice of the decisions of the Department on requests for extensions will be published in the FEDERAL REGISTER.

(c) Each request for an extension should be addressed to the Commissioner of Food and Drugs and should give:

(1) The name and chemical composition of the pesticide chemical for which extension is requested.

(2) A list of uses for which extension is requested and evidence that these uses were registered under the Federal Insecticide, Fungicide, and Rodenticide Act prior to May 1, 1955.

(3) Information about the amounts of residues that are expected to remain on raw agricultural commodities from these uses.

(4) Available information which indicates that these residues will not jeopardize the public health.

(5) A statement of the reason(s) a tolerance or exemption from the requirement of a tolerance has not been requested.

(d) In order that decisions on requests for extensions may be published before July 22, 1955, requests and supporting data should be received by June 27, 1955.

(e) Use during the 1955 growing season of a pesticide chemical for which extension is granted may yield a raw agricultural commodity which bears residues of the chemical. In such case, the raw agricultural commodity will not be considered adulterated within the meaning of the act even though it is marketed after the growing season, provided the commodity bearing such residues would have been legal in interstate commerce during the 1955 growing season.

(f) The Department believes that extensions beyond October 31, 1955, would lead to confusion in 1956. It recommends that States prepare spray schedules for the 1956 growing season which direct (1) pesticide uses that leave no residues at time of harvest or (2) the use only of pesticides for which tolerances have been established or exemptions granted under the Federal Food, Drug, and Cosmetic Act.

§ 3.41 *Pesticide chemicals; extended dates on which statute shall become fully effective.* (a) The amendment in clause (2) of section 402 (a) of the Federal Food, Drug, and Cosmetic Act shall become effective on the dates specified for the following pesticide chemicals:

(1) The effective date for Aramite (2-(*p-tert*-butylphenoxy) isopropyl-2-chloroethyl sulfite) shall be September 30, 1955, unless a tolerance is established for Aramite before that date, in which case the effective date shall be the date on which the regulation establishing such tolerance is published in the FEDERAL REGISTER.

(2) Effective date October 31, 1955:

Acrylonitrile: As a fumigant.
Aldrin:
  Apples, pears, and quinces.
  Avocados and papayas.
  Berries of the bramble type.
  Blueberries.
  Cherries.
  Citrus fruits (including grapefruit, lemons, oranges, and tangerines).
  Cranberries.
  Currants.
  Dates.
  Figs.
  Gooseberries.
  Grapes.
  Guavas.
  Peaches, nectarines, apricots, and mangoes.
  Pineapples.
  Plums and prunes.
  Strawberries.
  Artichokes.
  Asparagus.
  Beans (including black-eyed peas and soybeans).
  Beets (garden variety), turnips and rutabagas (including tops).
  Beets, sugar (including tops).
  Broccoli, Brussels sprouts, kohlrabi.
  Cabbage and cauliflower.
  Carrots, horseradish, parsnips, and radishes (including tops).
  Celery.
  Collards, kale, mustard greens, spinach, and Swiss chard.
  Corn, grain (including sweet, field, and popcorn).
  Corn fodder or forage.
  Cucumbers and summer squash.
  Eggplant, peppers, and pimentos.
  Endive (escarole), lettuce, and salsify.
  Melons (including cantaloupes, muskmelons, watermelons), pumpkins, winter squash.
  Okra.
  Onions (including leeks, shallots, and garlic).
  Parsley and watercress.
  Peanuts.
  Peas and cowpeas (including forage).
  Tomatoes.
  Grains (including oats, rye, barley, wheat, and rice).
  Buckwheat.
  Grain forage.
  Nuts (including pecans, almonds, hazelnuts, walnuts, hickory nuts).
  Legumes for forage (including clovers, alfalfa, soybean hay, peanut hay, and lespedeza).
  Grass crops (pasture and range grass, timothy, grass hay).
  Mint, spearmint, and peppermint.
  Sorghums.
  Sorghum forage.
Benzene hexachloride:
  Wheat.
  Oats.
  Garlic.
  Blueberries.
  Meat.
  Forage crops (alfalfa and clover).
Butoxy polypropylene glycol: In animal fly sprays.
Calcium cyanamide:
  Lettuce.
  Celery.
  Beans.
  Tomatoes.
  Potatoes.
  Cabbage and other crucifers.
  Asparagus.
  Hops.
  Small grains.
  Peas.
  Timothy hay.
  Stone fruits.
Calcium cyanide: As grain fumigant.
Carbon bisulfide: As grain fumigant.
Carbon tetrachloride: As grain fumigant.
Captan:
  Citrus fruits (grapefruit, lemons, limes, oranges, tangerines).
  Pineapples.
  Beans (green beans, lima beans, black-eyed peas).
  Peas.
  Potatoes.
  Apples, pears, quinces.
  Grapes.
  Strawberries.
  Cucumbers, summer squash.
  Eggplant, peppers.
  Melons (cantaloupes, watermelons).
  Pumpkins, winter squash.
  Tomatoes.
  Peaches, nectarines, apricots, mangoes.
  Plums, prunes.
  Celery.
  Collards, spinach.
  Lettuce.
  Cherries (sweet and sour).
Chlordane:
  Meat.
  Forage crops (including grass).
  Sweetpotatoes.
  Grains.
  Cottonseed.
  Sugarcane.
Chlorobenzilate (ethyl-4,4'-dichlorobenzilate):
  Apples.
  Pears.
Chloropicrin: As grain fumigant.
Copper carbonate, basic: Pears.
DDT:
  Forage crops (including alfalfa, clovers, peanuts, and other legumes).
  Corn and similar forage.
  Meat.
  Grain.
  Oranges.
Dieldrin:
  Avocados and papayas.
  Berries of the bramble type.
  Blueberries.
  Citrus fruits (including grapefruit, lemons, oranges, and tangerines).
  Cranberries.
  Currants.
  Dates.
  Figs.
  Gooseberries.
  Grapes.
  Guavas.
  Mangoes.
  Pineapples.
  Plums and prunes.
  Strawberries.
  Artichokes.
  Asparagus.

  - Beans (including black-eyed peas and soybeans).
  - Beets (garden variety), turnips, and rutabagas (including tops).
  - Beets, sugar (including tops).
  - Broccoli, brussels sprouts, kohlrabi.
  - Cabbage and cauliflower.
  - Carrots, horseradish, parsnips, and radishes (including tops).
  - Celery.
  - Collards, kale, mustard greens, spinach, and Swiss chard.
  - Corn, grain (including sweet, field, and popcorn).
  - Corn fodder or forage.
  - Cucumbers and summer squash.
  - Eggplant, peppers, and pimientos.
  - Endive (escarole), lettuce, salsify.
  - Melons (including cantaloupes, muskmelons, watermelons), pumpkins, and winter squash.
  - Okra.
  - Parsley and watercress.
  - Peanuts.
  - Peas and cowpeas (including forage).
  - Potatoes and sweetpotatoes.
  - Tomatoes.
  - Grains (including oats, rye, barley, wheat, rice).
  - Buckwheat.
  - Grain forage.
  - Nuts (including pecans, almonds, hazelnuts, walnuts, hickory nuts).
  - Legumes for forage (including clovers, alfalfa, soybean hay, peanut hay, lespedeza).
  - Grass crops (pasture and range grass, timothy, grass hay).
  - Mint, spearmint, and peppermint.
  - Sorghum.
  - Sorghum forage.
- Endrin:
  - Cabbage.
  - Sugar beets.
- EPN (*O*-ethyl-*O*-paranitrophenyl benzene thiophosphonate):
  - Grapes.
  - Nuts (including pecans, walnuts, and almonds).
  - Tomatoes.
  - Olives.
  - Onions.
  - Cottonseed.
  - Sugar beets.
- Ethylene dibromide: As grain and soil fumigant.
- Ethylene dichloride: As grain fumigant.
- Ferbam: Almonds.
- Heptachlor:
  - Alfalfa, clover, and sweet clover.
  - Beets, including sugar beets.
  - Cabbage, brussels sprouts, kohlrabi, and cauliflower.
  - Corn.
  - Cotton.
  - Pasture and range grass.
  - Onions.
  - Peanuts.
  - Peas.
  - Sugarcane.
  - Sweetpotatoes.
  - Turnips.
- Hydrocyanic acid: As a fumigant for grains, dried peas and beans, and nut meats.
- Karathane (2,6-dinitro-6-caprylphenyl crotonate):
  - Apples.
  - Pears.
  - Almonds.
  - Cantaloup.
  - Cucumbers.
  - Squash.
- Karmex DW (3-(3,4-dichlorophenyl)-1,1-dimethyl urea): Cottonseed.
- Karmex W (3-(parachlorophenyl)-1,1-dimethyl urea):
  - Pineapple.
  - Asparagus.
  - Onions.
  - Sugarcane.
- Lindane:
  - Cranberries.
  - Cantaloups.
  - Watermelons.
  - Grain (from treating storage bins).
  - Meat.
  - Walnuts.
  - Forage crops (alfalfa, clover).
  - Sweetpotatoes and yams.
- Malathion:
  - Alfalfa.
  - Apples.
  - Apricots.
  - Avocados.
  - Barley.
  - Beans.
  - Beets.
  - Blueberries.
  - Broccoli.
  - Brussels sprouts.
  - Cabbage.
  - Cauliflower.
  - Celery.
  - Cherries.
  - Citrus.
  - Clover.
  - Cranberries.
  - Cucumbers.
  - Currants.
  - Dandelions.
  - Dates.
  - Dewberries.
  - Eggplant.
  - Gooseberries.
  - Grapes.
  - Guavas.
  - Kale.
  - Kohlrabi.
  - Lettuce.
  - Mangoes.
  - Melons.
  - Mustard.
  - Oats.
  - Onions.
  - Passion fruit.
  - Pasture grass.
  - Peaches.
  - Pears.
  - Pecans.
  - Peas.
  - Peppers.
  - Pineapples.
  - Plums.
  - Potatoes.
  - Prunes.
  - Raspberries.
  - Rutabagas.
  - Spinach.
  - Squash.
  - Strawberries.
  - Sweet corn.
  - Tomatoes.
  - Turnips.
  - Walnuts.
  - Wheat.
- Maleic hydrazide:
  - Potatoes.
  - Onions.
- Maneb:
  - Almonds.
  - Beans.
  - Carrots.
  - Celery.
  - Cranberries.
  - Cucumbers.
  - Figs.
  - Grapes.
  - Onions.
  - Peaches.
  - Potatoes.
  - Spinach.
  - Tomatoes.
- Methoxychlor:
  - Carrots.
  - Currants.
  - Gooseberries.
  - Pasture grasses.
  - Forage legumes (alfalfa, clovers, peanuts, cowpeas, soybeans).
  - Peanuts.
  - Mint.
  - Meat.
  - Grains.
- Methyl bromide: As a fumigant.
- Ovotran (parachlorophenyl parachlorobenzene sulfonate):
  - Apples.
  - Citrus.
  - Melons.
  - Peaches.
  - Pears.
  - Plums.
  - Prunes.
- Parathion:
  - Forage crops (alfalfa, clover, peas, pangola grass, timothy, vetch).
  - Field crops (barley, corn, oats, wheat).
  - Hops.
  - Olives.
- Phygon (2,3-dichloro-1,4-napthoquinone):
  - Celery.
  - Tomatoes.
- Piperonyl butoxide: Grains (from storage treatment).
- Potassium cyanate: As weed-killer spray, resulting in residues on asparagus, onions, peas, tomatoes, cottonseed, soybeans, field beans.
- Sodium orthophenylphenate tetrahydrate:
  - Apples.
  - Pears.
- Sulfoxide (*n*-octylsulfoxide of isosafrole): In fly sprays.
- Sulphenone (parachlorophenyl phenyl sulfone):
  - Apples.
  - Pears.
  - Peaches.
- Systox:
  - Apples.
  - Pears.
  - Oranges.
  - Lemons.
  - Grapefruit.
  - Grapes.
  - Strawberries.
  - Broccoli.
  - Brussels sprouts.
  - Cabbage.
  - Cauliflower.
  - Muskmelons.
  - Potatoes.
  - Almonds.
  - English walnuts.
  - Alfalfa.
  - Clover.
  - Hops.
- TDE: Meat.
- Toxaphene:
  - Cranberries.
  - Plums and prunes.
  - Beets.
  - Turnips.
  - Rutabagas.
  - Sugar beets.
  - Horseradish.
  - Parsnips.
  - Collards.
  - Kale.
  - Mustard greens.
  - Spinach.
  - Swiss chard.
  - Peppers.
  - Pimentos.
  - Cowpeas.
  - Grains (including oats, rye, barley, wheat, rice, sorghum grain).
  - Buckwheat.
  - Nuts (including pecans, walnuts, hazelnuts, hickory nuts).
  - Legumes for forage (including clovers, alfalfa, soybean hay, peanut hay, lespedeza, cowpea hay).
  - Grass crops (pasture and range grass, timothy, grass hay).
  - Grain forage (including corn and sorghum).
  - Sugarcane.
  - Meat.
- Trichloroethane: As grain fumigant.

Zineb:
  Pecans.
  Hops.
  Mushrooms.
Ziram:
  Almonds.
  Pecans.
  Strawberries.

(b) The extensions prescribed in paragraph (a) of this section apply only to the extent that tolerances or exemptions under section 408 of the Federal Food, Drug, and Cosmetic Act shall not have been established prior to the effective dates as extended.

§ 3.42 *Pesticide chemicals; additional extended dates on which statute shall become fully effective; denial of requests for extensions.* (a) Conditions exist which necessitate the following extensions. The amendment in clause (2) of section 402 (a) of the Federal Food, Drug, and Cosmetic Act shall become effective on the dates specified for the following pesticide chemicals:

(1) Effective date October 31, 1955:
Alkyl dimethyl benzyl ammonium chloride: On apples.
Allethrin: On livestock.
Chloro IPC: Preemergence use on spinach.
Dimite: On fruits and vegetables.
Ethylene dichloride: On citrus and strawberries.
Ethylene oxide: On spices.
Piperonyl butoxide: On apples, citrus, livestock, pears, tomatoes.
Pyrethrins: On apples, citrus, grains (stored), livestock, pears, tomatoes.
Sodium dimethyldithiocarbamate: On cantaloups.
Trichloroethane: On citrus, strawberries.
(2) Effective date January 22, 1956:
Diphenyl: On citrus.

(b) Extension is not granted for the following indicated uses of the listed pesticide chemicals. Conditions do not exist that necessitate extension for these uses.

Hexamethylenetetramine: On citrus.
Methoxychlor: In milk.
Rotenone: Unspecified uses.
Sodium O-phenylphenate: On citrus.

(c) The extensions prescribed in paragraph (a) of this section apply only to the extent that tolerances or exemptions under section 408 of the Federal Food, Drug, and Cosmetic Act shall not have been established prior to the effective dates as extended.

(Secs. 402, 408, 68 Stat. 511, 517; 21 U. S. C. 342, 346a)

§ 3.43 *Labeling of drug preparations containing salicylates.* (a) Because salicylate preparations enjoy widespread use as analgesics and such articles are ordinarily not toxic in the amounts required for producing an analgesic action, they are frequently regarded by the public as harmless. Actually, salicylates are capable of causing injury and even death when consumed in excessive quantities. Salicylate preparations have caused a number of deaths through accidental misuse by both adults and children, which might have been avoided had the users been aware of their potential hazards.

(b) On the basis of a study and conclusions by the Medical Advisory Panel on the Accidental Ingestion and Misuse of Salicylate Preparations by Children, under date of February 14, 1955, and in the interest of protecting the public health, the following recommendations are made concerning the labeling that should be employed for salicylate preparations to meet the requirements of section 502 (f) (1) and (2) of the Federal Food, Drug, and Cosmetic Act.

(1) The labels of all packages of salicylate preparations that are labeled with directions for use should bear, clearly visible and in bold-face type, some such statement as one of the following:

(i) "Warning—Keep out of the reach of children"; or

(ii) "Warning—Keep this and all medications out of the reach of children."

(2) In lieu of specific dosage recommendations for children under three years of age, the labeling of salicylate preparations for oral use should bear a statement such as: "For children under 3 years of age, consult your physician."

(c) The labeling recommendations in paragraph (b) of this section are applicable to preparations containing aspirin, salicylamide, salicylic acid and its salts, and other salicylic acid derivatives used as analgesics, except as provided in paragraph (d) of this section.

(d) To the extent shown in this paragraph, the labeling recommendations of paragraph (b) of this section do not apply to the following preparations.

(1) Paragraph (b) (1) of this section does not apply to wintergreen oil subject to § 3.35.

(2) Paragraph (b) (1) of this section does not apply to effervescent salicylate preparations since such preparations do not lend themselves to accidental use or overdosage.

(3) Paragraph (b) (1) and (2) of this section does not apply to preparations of para-aminosalicylic acid and its salts, which are not labeled with directions for use as analgesics.

(e) This statement in no way exempts salicylate preparations from complying in all other respects with the requirements of the Federal Food, Drug, and Cosmetic Act.

(f) Copies of the recommendations adopted by the Medical Advisory Panel on the Accidental Ingestion and Misuse of Salicylate Preparations by Children, which convened on February 14, 1955, may be obtained from the Department of Health, Education, and Welfare, Food and Drug Administration, upon request.

(g) Six months will be allowed for modification of existing labeling to comply with this statement.

(Sec. 502, 52 Stat. 1050, as amended; 21 U. S. C. 352)

§ 3.44 *Pesticide chemicals; further extended dates on which statute shall become fully effective.* The amendments in clause (2) of section 402 (a) of the Federal Food, Drug, and Cosmetic Act shall become fully effective on the dates specified for the pesticide chemicals named in this section. The extensions prescribed in this section apply only to the extent that tolerances or exemptions from tolerances under section 408 of the act shall not have been established prior to the effective dates as extended. This section supersedes any extended effective dates for the same pesticide chemicals for use on the same raw agricultural commodities previously published in §§ 3.41 and 3.42. All further changes in extended effective dates on the same or other pesticide chemicals will be published as amendments to this section.

(a) (1) Effective date January 22, 1956:
Aldrin: For use on berries of the bramble type, blueberries, dates, pineapples, strawberries, beans (including black-eyed peas and soybeans), beets (sugar, including tops), broccoli, cabbage, carrots, corn, cucumbers, onions, peanuts, peas and cowpeas (including forage), tomatoes, grains (including oats, rye, barley, wheat, rice), buckwheat, grain forage, legumes for forage (including clovers, alfalfa, peanut hay), grass crops (pasture and range grass), mint (including spearmint and peppermint).
Allethrin: On livestock.
Calcium cyanide: As a grain fumigant.
Chlordane: On forage crops (including grass), sweetpotatoes, grains, cottonseed, sugarcane.
Dieldrin: On berries of the bramble type, blueberries, citrus fruits, grapes, plums and prunes, strawberries, beans (including black-eyed peas and soybeans), cabbage, corn, cucumbers, lettuce, melons (including cantaloups and muskmelons), peanuts, peas and cowpeas, potatoes and sweetpotatoes, grains (including oats, rye, barley, wheat, rice), buckwheat, grain forage, legumes for forage (including clovers, alfalfa, peanut hay), grass crops (pasture and range grass, timothy, grass hay), sorghum, sorghum forage.
Endrin: On cabbage, sugar beets.
EPN (*O*-ethyl-*O*-paranitrophenyl benzene thiophosphonate): On grapes, nuts (including pecans, walnuts, and almonds), tomatoes, olives, onions, cottonseed, sugar beets.
Ethylene dibromide: As a soil fumigant.
Ferbam: On almonds.
Hydrocyanic acid: As a fumigant for grains, dried peas and beans, and nut meats.
Lindane: On forage crops (alfalfa, clover), meat, grain (from treating storage bins).
Methoxychlor: On carrots, currants, gooseberries, pasture grasses, forage legumes (alfalfa, clovers, peanuts, cowpeas, soybeans), peanuts, mint, meat, grains.
Methyl bromide: As a fumigant.
Parathion: On forage crops (alfalfa, clover, peas, pangola grass, timothy, vetch), field crops (barley, corn, oats, wheat), hops, olives.
Phygon (2,3-dichloro-1,4-naphthoquinone): On celery, tomatoes.
Piperonyl butoxide: On apples, citrus, livestock, pears, tomatoes, grains.
Pyrethrins: On apples, citrus, grains (stored), livestock, pears, tomatoes.
Toxaphene: On cranberries, plums and prunes, beets, turnips, rutabagas, sugar beets, horseradish, parsnips, collards, kale, mustard greens, spinach, Swiss chard, peppers, pimentos, cow peas, grains (including oats, rye, barley, wheat, rice, sorghum grain), buckwheat, nuts (including pecans, walnuts, hazelnuts, hickory nuts), legumes for forage (including clovers, alfalfa, soybean hay, peanut hay, lespedeza, cow pea hay), grass crops (pasture and range grass, timothy, grass hay), grain forage (including corn and sorghum), sugarcane, meat.
Zineb: On pecans, hops, mushrooms.
Ziram: On almonds, pecans, strawberries.

(2) Effective date March 1, 1956:
Acrylonitrile: As a fumigant.
Benzene hexachloride: In meat.
Butoxypolypropylene glycol: In animal fly sprays.
Captan: Post-harvest use on potatoes.
Carbon bisulfide: As a grain fumigant.
Carbon tetrachloride: As a grain fumigant.
Chlordane: In meat.
Chloropicrin: As a grain fumigant.

Copper carbonate, basic: On pears.
DDT: In meat.
Ethylene dibromide: As a fumigant.
Ethylene dichloride: As a grain fumigant, on citrus and strawberries.
Ethylene oxide: On spices.
Malathion: On citrus.
Ovotran (*p*-chlorophenyl parachlorobenzene sulfonate): On citrus.
Sodium-orthophenylphenate tetrahydrate: On apples and pears.
Sodium-*o*-phenylphenate: On citrus.
TDE: In meat.
Trichloroethane: As a grain fumigant, on citrus and strawberries.

(Secs. 402, 408, 68 Stat. 511, 517; 21 U. S. C. 342, 346a)

§ 3.45 *Sterilization of drugs by irradiation.* There is a current interest in the utilization of newly developed sources of radiation for the sterilization of drugs. Prior to the marketing of a drug sterilized by such means, it is necessary in the interest of protecting the public health to establish by adequate investigations that the irradiation treatment does not cause the drug to become unsafe or otherwise unsuitable for use. Accordingly, all drug products, including injections, ophthalmic solutions, surgical sutures, and surgical dressings sterilized by means of irradiation are regarded as new drugs within the meaning of section 201 (p) of the Federal Food, Drug, and Cosmetic Act. An effective new-drug application pursuant to section 505 of the act is therefore a prerequisite to interstate shipment of such articles, except as provided by section 505 (i).

(Secs. 201, 505, 52 Stat. 1042, 1052; 21 U. S. C. 321, 355)

PART 4—OFFICIAL RECORDS AND INFORMATION

§ 4.1 *Disclosure of official records and information.* (a) No officer or employee of the Food and Drug Administration or of any other office or establishment in the Department of Health, Education, and Welfare—except as otherwise specifically authorized in accordance with paragraph (c) of this section or except in the discharge of his official duties under the laws administered by the Food and Drug Administration—shall produce or disclose to any person, or before any tribunal, directly or indirectly, whether in response to a subpoena or otherwise, any record (including any file, letter, application, report, work sheet, or other paper or document) pertaining to the functions of the Food and Drug Administration, or any information acquired from any such record or otherwise acquired in the discharge of his official duties.

(b) Whenever a subpoena or a subpoena duces tecum, in appropriate form, has been lawfully served upon an officer or employee of the Food and Drug Administration commanding the production of any such record or the giving of any such information, such officer or employee will, unless otherwise specifically authorized in accordance with paragraph (c), appear in response thereto and respectfully decline to produce the record or information specified therein, on the ground that disclosure of such record or information is prohibited by this section.

(c) A person who desires the disclosure of any such record or information may make written request therefor, verified by oath, directed to the Commissioner of Food and Drugs, setting forth his interest in the matter sought to be disclosed and specifically designating the use to which such records or information will be put in the event of compliance with such request; *Provided,* That a written request therefor made by a health, food or drug officer, prosecuting attorney or member of the judiciary of any State, Territory or political subdivision thereof, acting in his official capacity, need not be verified by oath. If it is determined by the Commissioner, or any other officer or employee of the Food and Drug Administration whom he may designate to act on his behalf for the purpose, that disclosure of any such record or information for the use so specifically designated will not be incompatible with the public interest and will not result in revealing confidential matters the request will be granted, and if testimony relating thereto is requested one or more employees of the Food and Drug Administration will be designated and directed to appear, in response to a subpoena or a subpoena duces tecum, and testify with respect thereto.

(Sec. 10, 29 Stat. 607, as amended, sec. 3, 44 Stat. 1102, sec. 9 (c) (1), 44 Stat. 1409, sec. 4, 49 Stat. 885, sec. 701 (a), 52 Stat. 1055; 15 U. S. C. 409 (c) (1), 21 U. S. C. 50, 64, 143, 371 (a))

PART 9—COLOR CERTIFICATION

Sec.

9.1 Definitions.
9.2 General specification for straight colors.
9.3 List of straight colors and specifications for their certification for use in food, drugs, and cosmetics.
9.4 List of straight colors and specifications for their certification for use in drugs cosmetics.
9.5 List of straight colors and specifications for their certification for use in externally applied drugs and cosmetics.
9.6 Mixtures which may be certified.
9.7 Sampling, storage, and packaging.
9.8 Requests for certification.
9.9 Certification.
9.10 Limitations of certificates.
9.11 Labeling.
9.12 Records of distribution.
9.13 Authority to refuse certification service.
9.14 Procedure for admitting colors to listing.
9.15 Fees.

AUTHORITY: §§ 9.1 to 9.15 issued under sec. 701 (a), 52 Stat. 1055; 21 U. S. C. 371 (a). Interpret or apply secs. 406 (b), 504, 604, 702, 706, 52 Stat. 1049, 1052, 1055, 1056, 1058; 21 U. S. C. 346 (b), 354, 364, 372, 376.

§ 9.1 *Definitions.* For the purposes of this part:

(a) The term "coal-tar color" means articles which (1) are composed of or contain any substance derived from coal tar, or any substance so related in its chemical structure to a constituent of coal tar as to be capable of derivation from such constituent; and (2) when added or applied to a food, drug, cosmetic, or the human body or any part thereof, are capable (alone or through reaction with other substance) of imparting color thereto.

(b) The term "straight color" means a coal-tar color listed in §§ 9.3, 9.4, or 9.5, and includes such impurities and substrata as are contained in such color.

(c) The term "mixture" means a coal-tar color made by mixing two or more straight colors, or one or more straight colors and one or more diluents.

(d) The term "diluent" means any component of a coal-tar color, except a straight color.

(e) The term "pure dye" means the coal-tar dye contained in a coal-tar color, exclusive of any intermediate or other impurity, or of any diluent or substratum contained therein.

(f) The term "substratum" means the substance on which the pure dye in a lake is extended.

(g) The term "alumina" means a suspension in water of precipated aluminum hydroxide.

(h) The term "blanc fixe" means a suspension in water of precipitated barium sulfate.

(i) The term "gloss white" means a suspension in water of co-preciptated aluminum hydroxide and barium sulfate.

(j) The term "mixed oxides" means the sum of the quantities of aluminum, iron, calcium, and magnesium (in whatever combination they may exist in a coal-tar color) calculated as aluminum trioxide, ferric oxide, calcium oxide, and magnesium oxide.

(k) The term "batch" means a quantity of coal-tar color which is set apart and held as a unit for the purpose of obtaining certification of such quantity.

(l) The term "batch number" means the number assigned to a batch by the person who requests certification thereof.

(m) The term "lot number" means an identifying number or symbol assigned to a batch by the Food and Drug Administration.

(n) The term "externally applied drugs and cosmetics" means drugs and cosmetics which are applied only to external parts of the body and not to the lips or any body surface covered by mucous membrane.

(o) The authorization contained in this part for the certification of coal-tar colors shall not be considered to authorize the certification of any coal-tar color for use in any article which is applied to the area of the eye. A coal-tar color used in any such article which is so applied shall be considered to be from a batch that has not been certified in accordance with this part, even though such color is from a batch that has been certified for other use.

(p) The term "area of the eye" means the area enclosed within the circumference of the supra-orbital ridge and the infra-orbital ridge, including the eyebrow, the skin below the eyebrow, the eyelids and the eyelashes, the conjunctival sac of the eye, the eyeball, and the soft areolar tissue that lies within the perimeter of the infra-orbital ridge.

(q) The definitions and interpretations of terms contained in section 201 of the act shall be applicable also to such terms when used in this part.

§ 9.2 *General specifications for straight colors.* No batch of a straight color listed in § 9.3, § 9.4, or § 9.5 shall be certified under this part unless:

(a) It is free from all impurities (other than those named in paragraph (b) of this section or in the specifications set forth in such section for such color) to the extent that such impurities can be avoided by good manufacturing practice.

(b) It conforms to the following specifications:

(1) In the case of a straight color listed in § 9.3:

Lead (as Pb), not more than 0.001 percent.

Arsenic (as As_2O_3), not more than 0.00014 percent.

Heavy metals (except Pb and As) (by precipitation as sulfides), not more than trace.

(2) In the case of a straight color listed in § 9.4 or §9.5:

Lead (as Pb), not more than 0.002 percent.

Arsenic (as As_2O_3), not more than 0.0002 percent.

Heavy metals (except Pb and As) (by precipitation as sulfides), not more than 0.003 percent.

(3) In the case of a straight color which contains a barium salt listed in § 9.4 or § 9.5—soluble barium (in dilute HCl) (as $BaCl_2$), not more than 0.05 percent.

§ 9.3 *List of straight colors and specifications for their certification for use in food, drugs, and cosmetics.* (a) A batch of a straight color listed in this section may be certified, in accordance with the provisions of the regulations in this part, for use in food (subject to the restrictions prescribed by paragraph (c) of this section), drugs, and cosmetics, if such batch conforms to the requirements of § 9.2 and to the specifications in this section set forth for such color.

FD&C Green No. 1

SPECIFICATIONS

Monosodium salt of 4-[4-(N-ethyl-p-sulfobenzylamino)-diphenylmethylene] - [1 - (N-ethyl-N-p-sulfoniumbenzyl) - $\Delta^{2,5}$ - cyclohexadienimine].

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.4 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

FD&C Green No. 2

SPECIFICATIONS

Disodium salt of 4-{[4-(N-ethyl-p-sulfobenzylamino)-phenyl] - (4-sulfonium-phenyl)-methylene}-[1-(N-ethyl-N-p-sulfobenzyl)-$\Delta^{2,5}$-cyclohexadienimine].

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.4 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Subsidiary dyes (as FD&C Green No. 1), not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

FD&C Green No. 3

SPECIFICATIONS

Disodium salt of 4-{[4-(N-ethyl-p-sulfobenzylamino)-phenyl]-(4-hydroxy-2-sulfoniumphenyl)-methylene}-[1 - (N-ethyl-N-p-sulfobenzyl)-$\Delta^{2,5}$-cyclohexadienimine].

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.4 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Subsidiary dyes, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

FD&C Yellow No. 1

SPECIFICATIONS

Disodium salt of 2,4-dinitro-1-naphthol-7-sulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.2 percent.

Ether extracts, not more than 0.1 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Martius Yellow, not more than 0.03 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

FD&C Yellow No. 2

SPECIFICATIONS

Dipotassium salt of 2,4-dinitro-1-naphthol-7-sulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Ether extracts, not more than 0.1 percent.

Chlorides and sulfates of potassium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Martius Yellow, not more than 0.03 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

FD&C Yellow No. 3

SPECIFICATIONS

1-Phenylazo-2-naphthylamine.

Volatile matter (at 80° C.), not more than 0.2 percent.

Sulfated ash, not more than 0.3 percent.

Water soluble matter, not more than 0.3 percent.

Matter, insoluble in carbon tetrachloride, not more than 0.5 percent.

Intermediates, not more than 0.05 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 99.0 percent.

Melting point, not less than 99° C.

FD&C Yellow No. 4

SPECIFICATIONS

1-o-Tolylazo-2-naphthylamine.

Volatile matter (at 80° C.), not more than 0.2 percent.

Sulfated ash, not more than 0.3 percent.

Water soluble matter, not more than 0.3 percent.

Matter, insoluble in carbon tetrachloride, not more than 0.5 percent.

Intermediates, not more than 0.05 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 99.0 percent.

Melting point, not less than 120° C.

FD&C Yellow No. 5

SPECIFICATIONS

Trisodium salt of 3-carboxy-5-hydroxy-1-p-sulfophenyl-4-p-sulfophenylazo-pyrazole.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.3 percent.

Phenylhydrazine-p-sulfonic acid, not more than 0.1 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Subsidiary dyes, not more than 3.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

FD&C Yellow No. 6

SPECIFICATIONS

Disodium salt of 1-p-sulfophenylazo-2-naphthol-6-sulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Subsidiary dyes, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

FD&C Red No. 1

SPECIFICATIONS

Disodium salt of 1-pseudocumylazo-2-naphthol-3,6-disulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.3 percent.

Ether extracts, not more than 0.2 percent.

Pseudo-cumidine, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Lower sulfonated dyes, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

Boiling range of crude pseudo-cumidine, or of pseudo-cumidine obtained by reduction of the dye, 220–245° C.

FD&C Red No. 2

SPECIFICATIONS

Trisodium salt of 1-(4-sulfo-1-naphthylazo)-2-naphthol-3,6-disulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.5 percent.

Ether extracts, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Subsidiary dyes, not more than 4.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

FD&C Red No. 3

SPECIFICATIONS

Disodium salt of 9-o-carboxyphenyl-6-hydroxy-2, 4, 5, 7-tetraiodo-3-isoxanthone.

Volatile matter (at 135° C.), not more than 12.0 percent.

Water, insoluble matter, not more than 0.2 percent.

Ether extracts, not more than 0.1 percent.

Chlorides and sulfates of sodium, not more than 2.0 percent.

Sodium carbonate, not more than 0.5 percent.

Sodium iodide, not more than 0.4 percent.

Mixed oxides, not more than 1.0 percent.

Permitted range of organically combined iodine in pure dye, free from water of crystallization, 56.8 to 58.5 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

FD&C Red No. 4

SPECIFICATIONS

Disodium salt of 2-(5-sulfo-2,4-xylylazo)-1-naphthol-4-sulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water, insoluble matter, not more than 0.3 percent.

Ether extracts, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Subsidiary dyes, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

FD&C Blue No. 1

SPECIFICATIONS

Disodium salt of 4-{[4-(N-ethyl-p-sulfobenzylamino)-phenyl] - (2-sulfoniumphenyl)-methylene}-[1-(N-ethyl-N-p-sulfobenzyl)-$\Delta^{2,5}$-cyclohexadienimine].

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 0.3 percent.

Ether extracts, not more than 0.4 percent.

Chlorides and sulfates of sodium, not more than 4.0 percent.

Sodium acetate, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Subsidiary dyes, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

FD&C Blue No. 2

SPECIFICATIONS

Disodium salt of 5, 5'-indigotindisulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluable matter, not more than 0.5 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 7.0 percent.

Mixed oxides, not more than 1.0 percent.

Lower sulfonated dyes, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

FD&C Violet No. 1

SPECIFICATIONS

Monosodium salt of 4-{[4-(N-ethyl-p-sulfobenzylamino)-phenyl]-[4-(N-ethyl-p-sulfoniumbenzylamino) - phenyl] - methylene} - (N,N - dimethyl - $\Delta^{2,5}$ - cyclohexadienimine).

Volatile matter (at 135° C.), not more than 8.0 percent.

Water-insoluble matter, not more than 0.3 percent.

Ether extracts, not more than 0.4 percent.

p-Dimethylaminobenzoic acid, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 4.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

The sum of the volatile matter, chlorides and sulfates of sodium, pure dye, and leuco base of the dye, not less than 95.0 percent.

LAKES

Any lake made by extending on a substratum of alumina, a salt prepared from one of the water soluble straight colors hereinbefore listed in this paragraph by combining such color with the basic radicle aluminum or calcium.

SPECIFICATIONS

Ether extracts, not more than 0.3 percent.

Soluble chlorides and sulfates (as sodium salts), not more than 2.0 percent.

Inorganic matter, insoluble in HCl, not more than 0.5 percent.

Intermediates, not more than 0.1 percent.

(b) Each lake made as prescribed under the caption "Lakes" in paragraph (a) of this section shall be considered to be a straight color and to be listed therein under the name which is formed as follows:

(1) The listed name of the color from which the lake is prepared;

(2) The name of the basic radicle combined in such color; and

(3) The word "Lake".

(For example, the name of a lake prepared by extending the aluminum salt prepared from FD&C Orange No. 1 upon the substratum would be FD&C Orange No. 1—Aluminum Lake.)

(c) No lake listed in paragraph (a) of this section shall be certified for any use in food except external application to shell eggs.

§ 9.4 *List of straight colors and specifications for their certification for use in drugs and cosmetics.* (a) A batch of a straight color listed in this section may be certified, in accordance with the provisions of this part, for use only in drugs and cosmetics, if such batch conforms to the requirements of § 9.2 and to the specifications set forth in this section for such color.

D&C Green No. 4

SPECIFICATIONS

Calcium salt of 4-{[4-(N-ethyl-p-sulfobenzylamino) -phenyl]-(4-sulfonium - phenyl)-methylene}-[1-(N-ethyl-N-p-sulfobenzyl)-$\Delta^{2,5}$-cyclohexadienimine].

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates (as calcium salts), not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Subsidiary dyes (as FD&C Green No. 1), not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

D&C Green No. 5

SPECIFICATIONS

Disodium salt of 1,4-bis(o-sulfo-p-toluino)-anthraquinone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

1,4-Dihydroxy-anthraquinone, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 15.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 75.0 percent.

D&C Green No. 6

SPECIFICATIONS

1,4-Bis-(p-toluino)-anthraquinone.

Volatile matter (at 135° C.), not more than 2.0 percent.

Sulfated ash, not more than 1.0 percent.

Water soluble matter, not more than 0.3 percent.

Matter, insoluble in carbon tetrachloride, not more than 1.5 percent.

Intermediates, not more than 0.5 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 96.0 percent.

Melting point, not less than 210° C.

D&C Green No. 7

SPECIFICATIONS

Monosodium salt of 4-{[4-(N-ethyl-p-sulfobenzylamino) - phenyl]-(o-chlorophenyl)-methylene}-1-(N-ethyl-N-p-sulfonium-benzyl-$\Delta^{2,5}$-cyclohexadienimine).

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 8.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride, not less than 80.0 percent.

D&C Green No. 8

SPECIFICATIONS

Trisodium salt of 10-hydroxy-3,5,8-pyrenetrisulfonic acid.

Volatile matter (at 135° C.), not more than 15.0 percent.

Water insoluble matter, not more than 0.5 percent.

Chloroform extract, not more than 0.5 percent.

Pyrene, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 20.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as calculated from organically combined sulfur), not less than 65.0 percent.

D&C Yellow No. 7

SPECIFICATIONS

3,6-Fluorandiol.

Volatile matter (at 135° C.), not more than 2.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkaline solution), not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 2.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 96.0 percent.

D&C Yellow No. 8

SPECIFICATIONS

Disodium salt 9-o-carboxyphenyl-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 8.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

D&C Yellow No. 9

SPECIFICATIONS

Dipotassium salt of 9-o-carboxyphenyl-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of potassium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

D&C Yellow No. 10

SPECIFICATIONS

Disodium salt of disulfonic acid of 2-(2-quinolyl)-1,3-indandione.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Quinaldine, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as calculated from organically combined nitrogen), not less than 82.0 percent.

D&C Yellow No. 11

SPECIFICATIONS

2-(2-Quinolyl)-1,3-indandione.

Volatile matter (at 135° C.), not more than 1.0 percent.

Sulfated ash, not more than 1.0 percent.

Matter insoluble in alcohol, not more than 0.5 percent.

Quinaldine, not more than 0.2 percent.

Pure dye (as calculated from organically combined nitrogen), not less than 96.0 percent.

Melting point, not less than 235° C.

D&C Red No. 5

SPECIFICATIONS

Disodium salt of 1-xylylazo-2-naphthol-3,6-disulfonic acid.

Volatile matter (at 135° C.), not more than 12.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Xylidine, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

D&C Red No. 6

SPECIFICATIONS

Monosodium salt of 4-(o-sulfo-p-tolylazo)-3-hydroxy-2-naphthoic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

D&C Red No. 7

SPECIFICATIONS

Calcium salt of 4-(o-sulfo-p-tolylazo)-3-hydroxy-2-naphthoic acid.

Volatile matter (at 135° C.), not more than 8.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Chlorides and sulfates (as calcium salts), not more than 6.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

D&C Red No. 8

SPECIFICATIONS

Monosodium salt of 1-(4-chloro-o-sulfo-5-tolylazo)-2-naphthol.

Volatile matter (at 135° C.), not more than 10.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Lake Red C Amine, not more than 0.2 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

D&C Red No. 9

SPECIFICATIONS

Barium salt of 1-(4-chloro-o-sulfo-5-tolylazo)-2-naphthol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Lake Red C Amine, not more than 0.2 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 87.0 percent.

D&C Red No. 10

SPECIFICATIONS

Monosodium salt of 2-(2-hydroxy-1-naphthylazo)-1-naphthalenesulfonic acid.

Volatile matter (135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Tobias acid, not more than 0.2 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

D&C Red No. 11

SPECIFICATIONS

Calcium salt of 2-(2-hydroxy-1-naphthylazo)-1-naphthalenesulfonic acid.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Tobias acid, not more than 0.2 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates (as calcium salts), not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

D&C Red No. 12

SPECIFICATIONS

Barium salt of 2-(2-hydroxy-1-naphthylazo)-1-naphthalenesulfonic acid.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Tobias acid, not more than 0.2 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

D&C Red No. 13

SPECIFICATIONS

Strontium salt of 2-(2-hydroxy-1-naphthylazo)-1-naphthalenesulfonic acid.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Tobias acid, not more than 0.2 percent.

beta-Naphthal, not more than 0.2 percent.

Chlorides and sulfates (as sodium salts), not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

D&C Red No. 14

SPECIFICATIONS

Monosodium salt of 1-o-carboxy-phenylazo-2-napthol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

beta-Napthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

D&C Red No. 15

SPECIFICATIONS

Barium salt of 1-o-carboxyphenylazo-2-naphthol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

D&C Red No. 16

SPECIFICATIONS

Calcium salt of 1-o-carboxphyenylazo-2-naphthol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates (as calcium salts), not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

D&C Red No. 17

SPECIFICATIONS

1-p-Phenylazophenylazo-2-naphthol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Insoluble matter (in toluene), not more than 3.0 percent.

Aniline, not more than 0.2 percent.

Amino-azo-benzene, not more than 0.2 percent.

beta-Naphthol, not more than 0.2 percent.

Sodium chloride, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

D&C Red No. 18

SPECIFICATIONS

1-Xylylazoxylylazo-2-naphthol.

Volatile matter (at 100° C.), not more than 2.0 percent.

Sulfated ash, not more than 2.0 percent.

Water soluble matter, not more than 0.5 percent.

Matter, insoluble in carbon tetrachloride, not more than 1.0 percent.

Chlorides and sulfates of sodium, not more than 1.0 percent.

Amino-azo-xylene, not more than 0.2 percent.

Xylidine, not more than 0.2 percent.

beta-Naphthol, not more than 0.2 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 95.0 percent.

D&C Red No. 19

SPECIFICATIONS

3-Ethochloride of 9-o-carboxyphenyl-6-diethylamino-3-ethylimino-3-isoxanthene.

Volatile matter (at 135° C.), not more than 5.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts (from acid solution), not more than 0.5 percent.

Diethyl-m-aminophenol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 2.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 92.0 percent.

D&C Red No. 20

SPECIFICATIONS

3-Ethoacetate of 9-o-carboxyphenyl-6-diethylamino-3-ethylimino-3-isoxanthene.

Volatile matter (at 135° C.), not more than 5.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts (from acid solution), not more than 0.5 percent.

Diethyl-m-aminophenol, not more than 0.2 percent.

Sodium acetate, not more than 2.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 92.0 percent.

D&C Red No. 21

SPECIFICATIONS

2,4,5,7-Tetrabromo-3,6-fluorandiol.

Volatile matter (at 135° C.), not more than 6.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkaline solution), not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 2.0 percent.

Mixed oxides, not more than 1.0 percent.

Free bromine, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye, 47.5–51.5 percent.

Pure dye (as determined gravimetrically), not less than 93.0 percent.

D&C Red No. 22

SPECIFICATIONS

Disodium salt of 2,4,5,7-tetrabromo-9-o-carboxyphenyl-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free bromine, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye, 44.5–48.5 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

D&C Red No. 23

SPECIFICATIONS

Dipotassium salt of 2,4,5,7-tetrabromo-9-o-carboxyphenyl-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 15.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of potassium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free bromine, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye (free from water or alcohol of crystallization), 42.0–46.0 percent.

Pure dye (as determined gravimetrically), not less than 80.0 percent.

D&C Red No. 24

SPECIFICATIONS

2,4,5,7-Tetrachloro-3,6-fluorandiol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkaline solution), nor more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Free chlorine, not more than 0.02 percent.

Permitted range of organically combined chlorine in pure dye, 28.0–32.0 percent.

Pure dye (as determined gravimetrically), not less than 90.0 percent.

D&C Red No. 25

SPECIFICATIONS

Disodium salt of 9-o-carboxylphenyl-2,4,5,7-tetrachloro-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free chlorine, not more than 0.02 percent.

Permitted range of organically combined chlorine in pure dye, 26.0–29.5 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

D&C Red No. 26

SPECIFICATIONS

Dipotassium salt of 9-o-carboxylphenyl-2,4,5,7-tetrachloro-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of potassium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free chlorine, not more than 0.02 percent.

Permitted range of organically combined chlorine in pure dye, 24.5–27.5 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

D&C Red No. 27

SPECIFICATIONS

2,4,5,7-tetrabromo-12,13,14,15 - tetrachloro-3,6-fluorandiol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkaline solution), not more than 0.5 percent.

Sodium chloride, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Free halogens, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye, 38.5–42.5 percent.

Permitted range of organically combined chlorine in pure dye, 16.0–19.0 percent.

Pure dye (as determined gravimetrically), not less than 90.0 percent.

D&C Red No. 28

SPECIFICATIONS

Disodium salt of 2,4,5,7-tetrabromo-9-(3,4,5,6-tetrachloro-o-carboxyphenyl)-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free halogens, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye 36.5–40.5 percent.

Permitted range of organically combined chlorine in pure dye, 16.0–18.0 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

D&C Red No. 29

SPECIFICATIONS

1,4,5,8,15-Pentabromo-2.7 - dicarboxy - 3,6-fluorandiol.

Volatile matter (at 135° C.), not more than 2.0 percent.

Sulfated ash, not more than 1.0 percent.

Insoluble matter (alkaline solution), not more than 0.3 percent.

Soluble matter (in 1 percent aqueous hydrochloric acid), not more than 2.0 percent.

Free bromine, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye, 47.0–51.0 percent.

Pure dye (as determined gravimetrically), not less than 95.0 percent.

D&C Red No. 30

SPECIFICATIONS

5,5′-Dichloro-3,3′-dimethyl-thioindigo.

Volatile matter (at 135° C.), not more than 5.0 percent.

Matter, insoluble in xylene, not more than 1.0 percent.

Sodium chloride, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

D&C Red No. 31

SPECIFICATIONS

Calcium salt of 3-hydroxy-4-phenylazo-2-naphthoic acid.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts (Isopropyl ether), not more than 0.5 percent.

Aniline, not more than 0.2 percent.

Chlorides and sulfates (as calcium salts), not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

D&C Red No. 33

SPECIFICATIONS

Disodium salt of 8-amino-2-phenylazo-1-naphthol-3,6-disulfonic acid.

Volatile matter (at 135° C.), not more than 6.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Aniline, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 10.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

D&C Red No. 34

SPECIFICATIONS

Calcium salt of 4-(1-sulfo-2-naphthylazo)-3-hydroxy-2-naphthoic acid.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts, not more than 0.5 percent.

Tobias acid, not more than 0.2 percent.

Chlorides and sulfates (as calcium salts), not more than 10.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

D&C Red No. 35

SPECIFICATIONS

1-(o-Nitro-p-tolylazo)-2-napthol.

Volatile matter (at 135° C.), not more than 2.0 percent.

Sulfated ash, not more than 1.5 percent.

Matter insoluble in toluene, not more than 1.5 percent.

2-Nitro-p-toluidine, not more than 0.2 percent.

beta-Napthol, not more than 0.2 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 95.0 percent.

Melting point, not less than 272° C.

D&C Red No. 36

SPECIFICATIONS

1 - (o-Chloro-p-nitrophenylazo)-2-naphthol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Sulfated ash, not more than 1.0 percent.

Matter insoluble in toluene, not more than 1.0 percent.

o-Chloro-p-nitroaniline, not more than 0.2 percent.

beta-Naphthol, not more than 0.2 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

D&C Red No. 37

SPECIFICATIONS

3-Ethostearate of 9-o-carboxyphenyl-6-diethylamino-3-ethylimino-3-isoxanthene.

Volatile matter (at 80° C.), not more than 2.0 percent.

Sulfated ash, not more than 3.0 percent.

Matter insoluble in benzene, not more than 0.5 percent.

Diethyl-m-aminophenol, not more than 0.2 percent.

Stearic acid (not part of the dye), not more than 50.0 percent.

Pure dye (as determined by titration with titanium trichloride) not less than 50.0 percent.

D&C Red No. 38

SPECIFICATIONS

3-Hydroxy-N-(m-nitrophenyl)-4-(o-nitro-p-tolylazo)-2-napthamide.

Volatile matter (at 135° C.) not more than 5.0 percent.

Sulfated ash, not more than 1.5 percent.

Matter, insoluble in nitrobenzene, not more than 0.5 percent.

2-Nitro-p-toluidine, not more than 0.2 percent.

3-Hydroxy-N-(m-nitrophenyl)-2-naphthamide, not more than 0.2 percent.

Pure dye (as calculated from organically combined nitrogen), not less than 90.0 percent.

D&C Red No. 39

SPECIFICATIONS

o-[p-(β,β'-dihydroxy-diethylamino)-phenylazo]-benzoic acid.

Volatile matter (at 100° C.), not more than 2.0 percent.

Matter insoluble in acetone, not more than 1.5 percent.

Ether extract (petroleum ether), not more than 0.5 percent.

N,N(β,β'-dihydroxy-diethyl)-aniline, not more than 0.2 percent.

Sulfated ash, not more than 1.5 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 95.0 percent.

D&C Orange No. 3

SPECIFICATIONS

Disodium salt of 1-phenylazo-2-napthol-6,8-disulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Aniline, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 8.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

D&C Orange No. 4

SPECIFICATIONS

Monosodium salt of 1-p-sulfophenylazo-2-naphthol.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

D&C Orange No. 5

SPECIFICATIONS

4,5-Dibromo-3,6-fluorandiol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkaline solution), not more than 0.5 percent.

Sodium chloride, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Free bromine, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye, 31.0–35.0 percent.

Pure dye (as determined gravimetrically), not less than 90.0 percent.

D&C Orange No. 6

SPECIFICATIONS

Disodium salt of 4,5-dibromo-9-o-carboxyphenyl-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free bromine, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye, 28.0–32.0 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

D&C Orange No. 7

SPECIFICATIONS

Dipotassium salt of 4,5-dibromo-9-o-carboxyphenyl-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of potassium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free bromine, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye, 26.0–30.0 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

D&C Orange No. 8

SPECIFICATIONS

4,5-Dichloro-3,6-fluorandiol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkaline solution), not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Free chlorine, not more than 0.02 percent.

Permitted range of organically combined chlorine in pure dye, 16.0–19.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

D&C Orange No. 9

SPECIFICATIONS

Disodium salt of 9-o-carboxyphenyl-4,5-dichloro-6-hydroxy-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free chlorine, not more than 0.02 percent.

Permitted range of organically combined chlorine in pure dye, 14.5–17.5 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

D&C Orange No. 10

SPECIFICATIONS

4,5-Diiodo-3,6-fluorandiol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkaline solution), not more than 0.5 percent.

Sodium chloride, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Free iodine, not more than 0.05 percent.

Permitted range of organically combined iodine in pure dye, 41.5–45.5 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

D&C Orange No. 11

SPECIFICATIONS

Disodium salt of 9-o-carboxyphenyl-6-hydroxy-4,5-diiodo-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Free iodine, not more than 0.05 percent.

Permitted range of organically combined iodine in pure dye, 38.5–42.5 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

D&C Orange No. 12

SPECIFICATIONS

Dipotassium salt of 9-o-carboxyphenyl-6-hydroxy-4,5-diiodo-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of potassium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free iodine, not more than 0.05 percent.

Permitted range of organically combined iodine in pure dye, 36.5–40.5 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

D&C Orange No. 13

SPECIFICATIONS

Diammonium salt of 9-o-carboxyphenyl-6-hydroxy-4,5-diiodo-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of ammonium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free iodine, not more than 0.05 percent.

Permitted range of organically combined iodine in pure dye, 39.0–43.0 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

D&C Orange No. 14

SPECIFICATIONS

4,5,15-Tribromo-2,7-dicarboxy-3,6-fluorandiol.

Volatile matter (at 135° C.), not more than 2.0 percent.

Sulfated ash, not more than 1.0 percent.

Insoluble matter (alkaline solution), not more than 0.3 percent.

Soluble matter (in 1 percent aqueous hydrochloric acid), not more than 2.0 percent.

Free bromine, not more than 0.02 percent.

Permitted range of organically combined bromine in pure dye 36.0–40.0 percent.

Pure dye (as determined gravimetrically), not less than 95.0 percent.

D&C Orange No. 15

SPECIFICATIONS

1,2-Anthraquinonediol.

Volatile matter (at 135° C.), not more than 2.0 percent.

Water soluble matter, not more than 1.5 percent.

Ether insoluble matter, not more than 1.0 percent.

Sodium chloride, not more than 1.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined gravimetrically), not less than 95.0 percent.

Melting point, not less than 285° C.

D&C Orange No. 16

SPECIFICATIONS

4,5-Dibromo-2,7-diiodo-3,6-fluorandiol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (alkaline solution), not more than 0.5 percent.

Sodium chloride, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Free halogens, not more than 0.05 percent.

Permitted range of organically combined bromine in pure dye, 20.0–23.0 percent.

Permitted range of organically combined iodine in pure dye, 32.0–36.0 percent.

Pure dye (as determined gravimetrically), not less than 90.0 percent.

D&C Orange No. 17

SPECIFICATIONS

1-(2,4-Dinitrophenylazo)-2-naphthol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Sulfated ash, not more than 1.0 percent.

Matter insoluble in toluene, not more than 1.5 percent.

2,4-Dinitroaniline, not more than 0.2 percent.

beta-Naphthol, not more than 0.2 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

D&C Brown No. 1

SPECIFICATIONS

Monosodium salt of 4-p-sulfophenylazo-2-(2,4-xylylazo)-1,3-resorcinol.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

m-Xylidine, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

D&C Blue No. 4

SPECIFICATIONS

Diammonium salt of 4-{[4-(N-ethyl-p-sulfobenzylamino) - phenyl] - (2 - sulfoniumphenyl)-methylene}-[1-(N-ethyl-N-p-sulfobenzyl)-$\Delta^{2,5}$-cyclohexadienimine].

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of ammonium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

D&C Blue No. 5

SPECIFICATIONS

Monosodium salt of 1-methylamino-4-(o-sulfo-p-toluino)-anthraquinone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 8.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as calculated from organically combined nitrogen or sulphur), not less than 80.0 percent.

D&C Blue No. 6

SPECIFICATIONS

Indigotin.

Volatile matter (at 135° C.), not more than 5.0 percent.

Sulfated ash, not more than 2.0 percent.

Matter, insoluble in dichlorhydrin, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Pure dye (as determined by titration with titanium trichloride) not less than 95.0 percent.

D&C Blue No. 7

SPECIFICATIONS

Monosodium salt of 4-{[4-(N-ethyl-benzylamino)-phenyl]-(5 - hydroxy-4-sulfo-2-sulfoniumphenyl) - methylene}-(N - ethyl - N-benzyl-$\Delta^{2,5}$-cyclohexadienimine).

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

m-Nitro-benzaldehyde, not more than 0.2 percent.

Benzylethylaniline, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 8.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 80.0 percent.

D&C Blue No. 8

SPECIFICATIONS

Calcium salt of 4-{[4-(N-ethylbenzylamino) - phenyl]-(5-hydroxy-4-sulfo - 2 - sulfoniumphenyl) - methylene}-(N-ethyl-N-benzyl-$\Delta^{2,5}$-cyclohexadienimine).

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

m-Nitro-benzaldehyde, not more than 0.2 percent.

Benzylethylaniline, not more than 0.2 percent.

Chlorides and sulfates (as calcium salts), not more than 8.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 80.0 percent.

D&C Blue No. 9

SPECIFICATIONS

3,3′-Dichloroindanthrene.

Volatile matter (at 135° C.), not more than 1.0 percent.

Sulfated ash, not more than 1.0 percent.

2-Amino anthraquinone, not more than 0.2 percent.

Matter extractable by alcoholic HCL, not more than 1.0 percent.

Permitted range of organically combined chlorine in pure dye, 13.0–14.8 percent.

Pure dye (as calculated from organically combined nitrogen), not less than 97.0 percent.

D&C Black No. 1

SPECIFICATIONS

Disodium salt of 8-amino-7-p-nitrophenylazo-2-phenylazo-1-naphthol-3,6-disulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Aniline, not more than 0.2 percent.

p-Nitroaniline, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 10.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

D&C Violet No. 2

SPECIFICATIONS

1-Hydroxy-4-p-toluino-anthraquinone.

Volatile matter (at 135° C.) not more than 2.0 percent.

Sulfated ash, not more than 1.0 percent.

Matter insoluble in carbon tetrachloride, not more than 1.5 percent.

p-Toluidine, not more than 0.2 percent.

Pure dye (as calculated from organically combined nitrogen), not less than 96.0 percent.

Melting point, not less than 185° C.

Lakes

Any lake, other than those listed in § 135.3, made by extending on a substratum of alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, rosin, aluminum benzoate, or any combination of two or more of these, (1) one of the straight colors (except lakes) listed in § 135.3 or hereinbefore listed in this paragraph, which color is a salt in which is combined the basic radicle sodium, potassium, aluminum, barium, calcium, strontium, or zirconium; or (2) a salt prepared from one of the straight colors (except lakes) listed in § 135.3, or hereinbefore listed in this paragraph, by combining such color with the basic radicle sodium, potassium, aluminum, barium, calcium, strontium, or zirconium.

SPECIFICATIONS

Ether extracts, not more than 0.5 percent.

Soluble chlorides and sulfates (as sodium salts), not more than 3.0 percent.

Intermediates, not more than 0.2 percent.

(b) Each lake made as prescribed under the caption "Lakes" in paragraph (a) of this section shall be considered to be a straight color and to be listed therein under the name which is formed as follows:

(1) The listed name of the color from which the lake is prepared, except that if such name contains the symbol "FD&C" such symbol shall be changed to "D&C";

(2) The name of the basic radicle combined in such color; and

(3) The word "Lake."

(For example, the name of a lake prepared by extending the color D&C Red No. 9 upon a substratum is "D&C Red No. 9—Barium Lake", and a lake prepared by extending the aluminum salt prepared from FD&C Green No. 1 upon a substratum other than alumina is "D&C Green No. 1—Aluminum Lake".)

§ 9.5 *List of straight colors and specifications for their certification for use in externally applied drugs and cosmetics.* (a) A batch of a straight color listed in this section may be certified, in accordance with the provisions of this part, for use in externally applied drugs and cosmetics, if such batch conforms to the requirements of § 9.2 and to the specifications set forth in this section for such color.

Ext D&C Yellow No. 1

SPECIFICATIONS

Monosodium salt of 4-m-sulfophenylazo-diphenylamine.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Chloroform soluble matter, not more than 0.5 percent.

Diphenylamine, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 7.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

Ext D&C Yellow No. 2

SPECIFICATIONS

Calcium salt of 4-m-sulfophenylazo-diphenylamine.

Volatile matter (at 135° C.), not more than 10.0 percent.

Chloroform soluble matter, not more than 0.5 percent.

Diphenylamine, not more than 0.2 percent.

Chlorides and sulfates (as calcium salts), not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

Ext D&C Yellow No. 3

SPECIFICATIONS

Monsodium salt of 5-hydroxy-3-methyl-4-phenylazo-1-p-sulfophenyl-pyrazole.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Aniline, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

Ext D&C Yellow No. 4

SPECIFICATIONS

Monosodium salt of 1-(4-chloro-o-sulfophenyl)-5-hydroxy-3-methyl-4-[p-(p-tolylsulfonoxy)-phenylazo]-pyrazole.

Volatile matter (at 135° C.), not more than 5.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

p-Aminophenol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 10.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

Ext D&C Yellow No. 5

SPECIFICATIONS

alpha-(o-Nitro-p-tolylazo)-acetoacetanilide.

Volatile matter (at 135° C.), not more than 2.0 percent.

Sulfated ash, not more than 1.0 percent.

Matter insoluble in toluene, not more than 1.0 percent.

2-Nitro-p-toluidine, not more than 0.2 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 96.0 percent.

Melting point, not less than 250° C.

Ext D&C Yellow No. 6

SPECIFICATIONS

Disodium salt of 5-(para-sulfo-phenylazo)-salicylic acid.

Volatile matter (at 135° C.), not more than 3.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Sulfanilic acid, not more than 0.2 percent.

Salicylic acid, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 15.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

Ext D&C Red No. 1

SPECIFICATIONS

Disodium salt of 8-acetamido-2-p-acetamidophenyazo-1-naphthol-3,6-disulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

p-Amino acetanilid, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

Ext D&C Red No. 2

SPECIFICATIONS

Trisodium salt of 1-o-carboxyphenylazo-2-naphthol-3,6 disulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

Ext D&C Red No. 3

SPECIFICATIONS

Disodium salt of 9-o-carboxyphenyl-6-(4-sulfo-o-toluino)-3-o-tolylimino-3-isoxanthene.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

o-Toluidine, not more than 0.2 percent.

Mixed oxides, not more than 1.0 percent.

Chlorides and sulfates of sodium, not more than 10.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 80.0 percent.

Ext D&C Red No. 4

SPECIFICATIONS

12,15-Dichloro-2,4,5,7-tetraiodo-3,6-fluorandiol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Ether extracts (from alkaline solution), not more than 0.5 percent.

Sodium chloride, not more than 3.0 percent.

Mixed oxides, not more than 1.0 percent.

Free halogens, not more than 0.02 percent.

Permitted range of organically combined iodine in pure dye, 54.0–58.0 percent.

Permitted range of organically combined chlorine in pure dye, 7.0–8.5 percent.

Pure dye (as determined gravimetrically), not less than 90.0 percent.

Ext D&C Red No. 5

SPECIFICATIONS

Disodium salt of 9-(3,6 dichloro-o-carboxyphenyl)-6-hydroxy-2,4,5,7-tetraiodo-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free halogens, not more than 0.02 percent.

Permitted range of organically combined iodine in pure dye, 51.5–55.5 percent.

Permitted range of organically combined chlorine in pure dye, 6.8–8.3 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

Ext D&C Red No. 6

SPECIFICATIONS

Dipotassium salt of 9-(3,6-dichloro-o-carboxyphenyl)-6-hydroxy-2,4,5,7-tetraiodo-3-isoxanthone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of potassium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Free halogens, not more than 0.02 percent.

Permitted range of organically combined iodine in pure dye, 50.0–54.0 percent.

Permitted range of organically combined chlorine in pure dye, 6.5–8.0 percent.

Pure dye (as determined gravimetrically), not less than 85.0 percent.

Ext D&C Red No. 7

SPECIFICATIONS

Monosodium salt of 3,4-dihydroxy-2-anthroquinonesulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Chlorides and sulfates of sodium, not more than 6.0 percent.

Mixed oxides, not more than 1.0 percent.

Free acid as H_2SO_4, not more than 0.01 percent.

Pure dye (by spectrophotometric determination), not less than 82.0 percent.

Ext D&C Red No. 8

SPECIFICATIONS

Monosodium salt of 4-(2-hydroxy-1-naphthylazo)-1-naphthalenesulfonic acid.

Volatile matter (at 135° C.), not more than 5.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

Ext D&C Red No. 9

SPECIFICATIONS

Calcium salt of 2-(1-napthylazo)-1-naphthol-5-sulfonic acid.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts, not more than 0.5 percent.

alpha-Naphthylamine, not more than 0.2 percent.

Chlorides and sulfates (as calcium salts), not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

Ext D&C Red No. 10

SPECIFICATIONS

Disodium salt of 2-(4-sulfo-1-naphthylazo)-1-naphthol-4-sulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

Ext D&C Red No. 11

SPECIFICATIONS

Disodium salt of 8-acetamido-2-phenylazo-1-naphthol-3,6-disulfonic acid.

Volatile matter (at 135° C.), not more than 5.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Aniline, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 10.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

Ext D&C Red No. 12

SPECIFICATIONS

Barium salt of 1-(3-sulfo-2-tolylazo)-2-naphthol.

Volatile matter (at 135° C.), not more than 5.0 percent.

Ether extracts, not more than 0.5 percent.

beta-Naphthol, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 90.0 percent.

Ext D&C Red No. 13

SPECIFICATIONS

Disodium salt of 1-p-phenylazo-phenylazo-2-naphthol-6,8-disulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Aniline, not more than 0.2 percent.

p-Aminoazobenzene, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 8.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

Ext D&C Red No. 14

SPECIFICATIONS

1-Xylylazo-2-naphthol.

Volatile matter (at 100° C.), not more than 0.5 percent.

Sulfated ash, not more than 0.3 percent.

Water-soluble matter, not more than 0.3 percent.

Matter insoluble in carbon tetrachloride, not more than 0.5 percent.

Xylidene, not more than 0.1 percent.

β-Naphthol, not more than 0.05 percent.

m-Xylidine in xylidine obtained by reduction of the dye, not more than 30.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 97.0 percent.

Boiling range of xylidine, obtained by reduction of the dye, 95 percent between 212°–232° C.

Ext D&C Blue No. 1

SPECIFICATIONS

3-Methochloride of 9-dimethylamino-3-methylimino-3-isophenothiazine.

Volatile matter (at 110° C.), not more than 16.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Dimethyl aniline, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 2.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

Ext D&C Blue No. 2

SPECIFICATIONS

Zinc chloride double salt of 3-methochloride of 9-dimethylamino-3-methylimino-3-isophenothiazine.

Volatile matter (at 110° C.), not more than 15.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Dimethyl aniline, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 2.0 percent.

Zinc chloride (not a part of the dye), not more than 1.0 percent.

Oxides of iron and aluminum, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 82.0 percent.

Ext D&C Blue No. 3

SPECIFICATIONS

Monosodium salt of 4-{[4-(N-ethyl-benzylamino) - phenyl] - [p - sulfo-o-sulfonium-phenyl]-methylene}-(N-ethyl-N-benzyl-$\Delta^{2,5}$-cyclohexadienimine).

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Benzylethylaniline, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 8.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 80.0 percent.

Ext D&C Blue No. 4

SPECIFICATIONS

Disodium salt of 4,8-diamino-1,5-dihydroxy-2,6-anthraquinone disulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

Chlorides and sulfates of sodium, not more than 10.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as calculated from organically combined sulfur or nitrogen), not less than 80.0 percent.

Ext D&C Blue No. 5

SPECIFICATIONS

1,4-Bis(amylamino)-anthraquinone.

Volatile matter (at 100° C.), not more than 2.0 percent.

Insoluble matter in carbon tetrachloride, not more than 1.0 percent.

Sulfated ash, not more than 0.5 percent.

Amylamine, not more than 0.2 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 96.0 percent.

Ext D&C Black No. 1

SPECIFICATIONS

Disodium salt of 8-anilino-5-[4-(5-sulfo-1-naphthylazo)-1-naphthylazo]-1-naphthalenesulfonic acid.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

alpha-Naphthylamine, not more than 0.2 percent.

5-(4-Amino-1-naphthylazo)-1-naphthalene sulfonic acid, not more than 2.0 percent.

Chlorides and sulfates of sodium, not more than 10.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 80.0 percent.

Ext D&C Green No. 1

SPECIFICATIONS

Ferric salt of 6-sodiumsulfo-1-isonitroso-1,2-naphthoquinone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Ether extracts, not more than 0.5 percent.

Water insoluble matter, not more than 1.0 percent.

Chlorides and sulfates of sodium, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

Ext D&C Violet No. 1

SPECIFICATIONS

Disodium salt of 1.5-bis(o-sulfo-p-toluino)-anthraquinone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

p-Toluidine, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 8.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 80.0 percent.

Ext D&C Violet No. 2

SPECIFICATIONS

Monosodium salt of 1-hydroxy-4-(o-sulfo-p-toluino)-anthraquinone.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water insoluble matter, not more than 1.0 percent.

Ether extracts, not more than 0.5 percent.

p-Toluidine, not more than 0.2 percent.

Chlorides and sulfates of sodium, not more than 8.0 percent.

Mixed oxides, not more than 1.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 80.0 percent.

Ext D&C Orange No. 1

SPECIFICATIONS

alpha-(o-Nitro-p-anisylazo)-o-aceto-acetotoluide.

Volatile matter (at 135° C.), not more than 2.0 percent.

Sulfated ash, not more than 1.0 percent.

Matter insoluble in toluene, not more than 1.0 percent.

2-Nitro-p-anisidine, not more than 0.2 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 96.0 percent.

Melting point, not less than 210° C.

Ext D&C Orange No. 2

SPECIFICATIONS

4,5-Dinitro-3,6-fluorandiol.

Volatile matter (at 100° C.), not more than 5.0 percent.

Ether extracts (alkaline solution), not more than 0.5 percent.

Sulfated ash, not more than 1.0 percent.

Insoluble matter (alkaline solution), not more than 1.0 percent.

Range of organically combined nitrogen in pure dye, 6.45 to 6.80 percent.

Pure dye (as determined gravimetrically), not less than 92.0 percent.

Ext D&C Orange No. 3

SPECIFICATIONS

Monosodium salt of 4-*p*-sulfophenylazo-1-naphthol.

Volatile matter (at 135° C.), not more than 10.0 percent.

Water-insoluble matter, not more than 0.3 percent.

Ether extracts, not more than 0.2 percent.

α-Naphthol, not more than 0.1 percent.

Chlorides and sulfates of sodium, not more than 4.0 percent.

Mixed oxides, not more than 1.0 percent.

Orange II, not more than 5.0 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 85.0 percent.

Ext D&C Orange No. 4

SPECIFICATIONS

1-*o*-Tolylazo-2-naphthol.

Volatile matter (at 100° C.), not more than 0.5 percent.

Sulfated ash, not more than 0.3 percent.

Water-soluble matter, not more than 0.3 percent.

Matter insoluble in carbon tetrachloride, not more than 0.5 percent.

o-Toluidine, not more than 0.05 percent.

β-Naphthol, not more than 0.05 percent.

Pure dye (as determined by titration with titanium trichloride), not less than 98.0 percent.

Melting point, not less than 128.0° C.

Lakes

Any lake made by extending on a substratum of alumina, blanc fixe, gloss white, clay, titanium dioxide, zinc oxide, talc, rosin, aluminum benzoate, or on any combination of two or more of these (1) one of the straight colors hereinbefore listed in this paragraph, which color is a salt in which is combined the basic radicle sodium, potassium, barium, or calcium; or (2) a salt prepared from one of the straight colors hereinbefore listed in this paragraph by combining such color with the basic radicle sodium, potassium, aluminum, barium, calcium, strontium, or zirconium.

SPECIFICATIONS

Ether extracts, not more than 0.5 percent.

Soluble chlorides and sulfates (as sodium salts), not more than 3.0 percent.

Intermediates, not more than 0.2 percent.

(b) Each lake made as prescribed under the caption "Lakes" in paragraph (a) of this section shall be considered to be a straight color and to be listed therein under the name which is formed as follows:

(1) The listed name of the color from which the lake is prepared;

(2 The name of the basic radicle combined in such color; and

(3) The word "Lake."

(For example, the name of a lake prepared by extending the color Ext D&C Yellow No. 2 upon a substratum is "Ext D&C Yellow No. 2—Calcium Lake," and a lake prepared by extending the barium salt prepared from Ext D&C Red No. 2 upon the substratum is "Ext D&C Red No. 2—Barium Lake.")

§ 9.6 *Mixtures which may be certified.* (a) A batch of a mixture which contains no straight color listed in § 9.4 or § 9.5 may be certified in accordance with the provisions of the regulations in this part, for use in food (subject to the restrictions prescribed in paragraph (d) of this section), drugs, and cosmetics, if:

(1) Each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture;

(2) Each diluent in such batch of mixture is harmless and suitable for use therein; and

(3) No diluent (except resins, natural gum, pectin and, in the case of mixtures which are aqueous solutions or aqueous pastes, sodium benzoate in a quantity of not more than 1/10 of 1 percent) in such mixture is a non-nutritive substance, unless such mixture is for external application to shell eggs, or for use in coloring a food specified in the requests for certification of such batch submitted in accordance with § 9.8 (c), and such diluent, in the usual process of manufacturing such food, is removed and does not become a component of such food.

(b) A batch of a mixture which contains no straight color listed in § 9.5, or which contains a diluent not permitted by paragraph (a) (3) of this section, may be certified in accordance with the provisions of this part, for use only in drugs and cosmetics, if:

(1) Each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture.

(2) Each diluent in such batch of mixture is harmless and suitable for use therein.

(c) A batch of a mixture which contains a straight color listed in § 9.5 may be certified in accordance with the provisions of this part, for use only in externally applied drugs and cosmetics, if:

(1) Each coal-tar color used as an ingredient in mixing such batch is from a previously certified batch and such color has not changed in composition in any manner whatever since such previous certification, except by mixing into such batch of mixture; and

(2) Each diluent in such batch of mixture is harmless and suitable for use therein.

(d) No mixture which contains a lake listed in § 9.3 shall be certified for any use in food except external application to shell eggs.

§ 9.7 *Sampling, storage, and packaging.* (a) A sample of a coal-tar color which is to accompany a request for certification submitted in accordance with § 9.8 shall be taken from the batch covered by such request only after such batch has been so thoroughly mixed as to be of uniform composition throughout. Immediately after such sample is taken it shall be closed in a package of such kind as to prevent change in the composition of such sample. Such package shall be labeled to show conspicuously the name and post office address of the person submitting such request, the name of such color, and the batch number and quantity of such batch.

(b) Immediately after such sample is taken such batch shall be stored in containers of such kind as to prevent change in the composition of such color, or closed in packages for shipment or delivery, and so held until such batch is certified or certification thereof is refused. If such batch is certified and at the time of certification such batch or any part thereof is so stored such storage shall be maintained until such batch or part is:

(1) Closed in such packages.

(2) Used by the person who obtained such certification as an ingredient in a batch of a mixture on which such person submits a request for certification in accordance with § 9.8, or

(3) Used by such person in coloring a food, drug, or cosmetic, in accordance with the use for which such batch was certified.

(c) The package in which a coal-tar color is closed for shipment or delivery shall be of such kind as to prevent change in the composition of such color, and shall be so closed or sealed that such package cannot be opened without destroying such package or seal.

(d) For the purposes of this part an unavoidable change in the moisture content of a coal-tar color caused by ordinary and customary exposure that occurs in good storage packing, and distribution practice, shall not be considered to be a change in the composition of such color.

§ 9.8 *Requests for certification.* (a) A request for certification of a batch of a coal-tar color shall be addressed to the Food and Drug Administration, Department of Health, Education and Welfare, Washington 25, D. C. A request from a foreign manufacturer shall be signed by such manufacturer and by an agent of such manufacturer who resides in the United States.

(b) Except in the case of a request submitted under paragraph (d) of this section, a person who requests the certification of a batch of a straight color shall submit as part of his request statements showing:

(1) Whether or not he manufactured such batch, and if he did not, the name and post office address of the manufacturer thereof;

(2) The name of such color, as listed in § 9.3, § 9.4, or § 9.5, and the batch number and quantity of such batch;

(3) In the case of a lake, the process whereby such lake is made, including the name or names of the substrata present and the quantity thereof used for such batch.

Such request shall be accompanied by a ¼-pound sample taken from such batch and accurately representative thereof, and by payment of the fee prescribed by § 9.15 (a) (1). Such person shall submit such additional information and samples as the Food and Drug Administration may require for the purpose of determining whether or not such batch complies with the requirements laid down by § 9.9 (a) for the issuance of a certificate.

(c) Except in the case of a request submitted under paragraph (d) of this section, a person who requests certification of a batch of a mixture shall submit as part of his request statements:

(1) To the effect that he mixed such batch;

(2) Showing the name of such mixture, and the batch number and quantity of such batch;

(3) Showing the lot number of each coal-tar color used as an ingredient in mixing such batch, the quantity of such color so used, and that such color has not changed in composition in any manner whatever since certification, except by mixing into such batch;

(4) Showing the name, quality, and quantity of each diluent used as an ingredient in mixing such batch;

(5) In case such mixture contains a diluent permitted by § 9.6 (a) (3) only because such mixture is for use in coloring shell eggs or such diluent does not become a component of a food colored by such mixture, specifying the name of the food for which such mixture is used;

(6) Describing fully the process of mixing, with special reference to the precautions taken to render such batch uniform in composition.

Such request shall be accompanied by a ⅛-pound sample (or if the mixture contains 2 percent or less of pure dye, a ¼-pound sample) taken from such mixed batch and accurately representative thereof, and by payment of the fee prescribed by § 9.15 (a) (2). Such person shall submit such additional information and samples as the Food and Drug Administration may require for the purpose of determining whether or not such mixed batch complies with the requirements laid down by § 9.9 (a) for the issuance of a certificate.

(d) A person who requests the certification of a batch made by repacking a coal-tar color from a batch previously certified under this part, shall submit as part of his request statements:

(1) To the effect that he made the batch on which he requests certification by repacking such color, and that such color has not changed in composition in any manner whatever since such previous certification; and

(2) Showing the lot number of such previously certified batch, the name of such repacked color, and the batch number and quantity of such repacked batch. Such request shall be accompanied by a ⅛-pound sample taken from such repacked batch and accurately representative thereof, and by payment of the fee prescribed by § 9.15 (a) (2). Such person shall submit such additional information and samples as the Food and Drug Administration may require for the purpose of determining whether or not such repacked batch complies with the requirements of § 9.9 (a) for the issuance of a certificate.

§ 9.9 *Certification.* (a) If the Food and Drug Administration determines, after such investigation as it considers to be necessary, that:

(1) A request submitted in accordance with § 9.8 appears to contain no untrue statement of a material fact;

(2) In the case of a straight color, such color conforms to the specifications set forth therefor in §§ 9.2, 9.3, 9.4, and 9.5;

(3) In the case of a mixture containing a diluent, such diluent is harmless and suitable for use therein; and

(4) The batch covered by such request otherwise appears to comply with this part, the Food and Drug Administration shall issue to the person who submitted such request a certificate showing the lot number assigned to such batch and that such batch, subject to the terms, conditions, and restrictions prescribed by § 9.10, is a certified batch for use in food, drugs, and cosmetics, or for use only in drugs and cosmetics, or for use only in externally applied drugs and cosmetics, as the case may be.

(b) If the Food and Drug Administration determines, after such investigation as it considers to be necessary, that a request submitted in accordance with § 9.8, or the batch of coal-tar color covered by such request, does not comply with the requirements laid down by paragraph (a) of this section for the issuance of a certificate, the Food and Drug Administration shall refuse to certify such batch and shall give notice thereof to the person who submitted such request, stating its reasons for refusal.

§ 9.10 *Limitations of certificates.* (a) If a certificate is obtained through fraud or misrepresentation of a material fact, such certificate shall not be effective, and coal-tar color from the batch on which such certificate was issued shall be considered to be from a batch that has not been certified in accordance with this part.

(b) If, between the time a sample of coal-tar color accompanying a request for certification is taken and the time a certificate covering the batch of such color is received by the person to whom it is issued, any such color becomes changed in composition in any manner whatever, such certificates shall not be effective with respect to such changed color, and such changed color shall be considered to be from a batch that has not been certified in accordance with this part.

(c) If, at any time after a certificate is received by the person to whom it is issued, any color from the batch covered by such certificate becomes changed in composition in any manner whatever, such certificate shall expire with respect to such changed color. After such expiration such color shall be considered to be from a batch that has not been certified in accordance with this part; except that such color shall not be so considered for the purpose of certifying a batch of a mixture in which such color was used as an ingredient, if such change resulted solely from such use.

(d) A certificate shall expire with respect to any coal-tar color covered thereby if the package in which such color was closed for shipment or delivery is opened, unless opened solely for repacking by the person to whom such certificate was issued. After such expiration such color shall be considered to be from a batch that has not been certified in accordance with this part; except that such color shall not be so considered:

(1) When such color is used, subject to the restrictions prescribed by paragraphs (f), (g), and (h) of this section, in coloring a food, drug, or cosmetic;

(2) For the purpose of certifying a batch made by repacking such color; or

(3) For the purpose of certifying a batch of a mixture in which such color is used as an ingredient.

(e) A certificate shall not be effective with respect to a package of coal-tar color, and such color shall be considered to be from a batch that has not been certified in accordance with this part, if such package is shipped or delivered under a label which does not bear all words, statements, and other information required by § 9.11 to appear thereon.

(f) If a mixture from a batch containing a diluent permitted by § 9.6 (a) (3) only because such diluent does not become a component of a food colored by such mixture is used in coloring another food, such mixture so used shall be considered to be from a batch that has not been certified in accordance with this part.

(g) If coal-tar color from a batch which was certified for use in drugs and cosmetics only is used in coloring a food; such color so used shall be considered to be from a batch that has not been certified in accordance with this part.

(h) If a coal-tar color from a batch which was certified for use only in externally applied drugs and cosmetics is used in food or in other drugs or other cosmetics, such color so used shall be considered to be from a batch that has not been certified in accordance with this part.

(i) If a coal-tar color from a batch containing any lake listed in § 9.3 is used in coloring any food except shell eggs, such color so used shall be considered to be from a batch that has not been certified in accordance with the regulations in this part.

§ 9.11 *Labeling.* (a) The label on each package of coal-tar color from a batch that has been certified in accordance with this part shall bear, in addition to other words, statements, and information required by or under authority of the act to appear on such label:

(1) The name of such color;

(2) The lot number of such batch unless, in the case of any mixture for household use which contains not more than 15 percent of pure dye and which, if it is liquid, is in packages containing not more than 2 fluid ounces, or, if it is solid, semisolid, or viscous, is in packages containing not more than 2 avoirdupois ounces, such lot number appears on the labeling or on each invoice accompanying shipments or deliveries of such mixture, or unless in the case of such mixture there appears on the label, a code number which the manufacturer has identified with the lot number by giving to the Food and Drug Administration written notice that such code number will be used in lieu of the lot number;

(3) The percentage of pure dye in such color as provided in paragraph (b) of this section; and,

(4) In case such batch was certified for use only in drugs and cosmetics, the statement "Not for use in coloring food"; or in case such batch was certified for use only in externally applied drugs and cosmetics, the statement "Not for use in coloring food, or in coloring any drug or cosmetic used internally or on the lips or any mucous membrane"; or in case such batch is a mixture containing a diluent permitted by § 9.6 (a) (3) only because such diluent does not become a component of a food colored by such mixture, the statement "Not for use in coloring any food except ____________" (the blank to be filled in by the name of such food); or in case such batch contains any lake listed in § 9.3 or any diluent permitted by § 9.6 (a) (3) only because such batch is for use in coloring shell eggs, the statement "Not for use in coloring any food except shell eggs."

(b) The statement of the percentage of pure dye in a coal-tar color shall express:

(1) The percentage of pure dye shown in the certificate covering such color; or

(2) The minimum percentage by weight of pure dye in such color.

Where the statement expresses the minimum percentage, no variation below the stated minimum shall be permitted, and variations above shall not be unreasonably large.

(c) The name by which a straight color is designated on its label shall be the name by which such color is listed in § 9.3, § 9.4, or § 9.5.

(d) No batch of a mixture shall be certified under this part if:

(1) The name of such mixture is false or misleading in any particular; or

(2) The name of such mixture is the same as or simulates the name of a previously certified batch of a mixture containing a different substance, or a different percentage of a pure dye; but this provision shall not apply if:

(i) The person who requests certification of such batch is the owner of such name and has given 3 months' written notice to the Food and Drug Administration specifying the change to be made in the composition of such mixture; or

(ii) Such change results from removal of a color from the listings in §§ 135.3, 135.4, and 135.5.

§ 9.12 *Records of distribution.* (a) The person to whom a certificate is issued shall keep complete records showing the disposal of all the coal-tar color from the batch covered by such certificate. Upon the request of any officer or employee of the Food and Drug Administration, or of any other officer or employee of the United States acting on behalf of the Secretary of Health, Education, and Welfare, such person, at all reasonable hours until at least 1 year after disposal of all such color, shall make such records available to any such officer or employee, and shall accord to such officer or employee full opportunity to make inventory of stocks of such color on hand and otherwise to check the correctness of such records.

(b) The records required to be kept by paragraph (a) of this section shall show:

(1) Each quantity used by such person from such batch and the date and kind of such use;

(2) The date and quantity of each shipment or delivery from such batch, and the name and post office address of the person to whom such shipment or delivery was made.

§ 9.13 *Authority to refuse certification service.* When it appears to the Secretary of Health, Education, and Welfare that a person has:

(a) Obtained a certificate through fraud or misrepresentation of a material fact;

(b) Falsified the records required to be kept by § 9.12; or

(c) Failed to keep such records, or to make them available, or to accord full opportunity to make inventory of stocks on hand or otherwise to check the correctness of such records, as required by such section,

the Secretary may immediately suspend service to such person under this part, and may continue such suspension unless and until such person shows adequate cause why such suspension should be terminated.

§ 9.14 *Procedure for admitting colors to listing.* (a) An application for the admission of a coal-tar color to listing in § 9.3, § 9.4, or § 9.5 shall be accompanied by:

(1) Full reports of investigations which are adequate to show whether or not such color is harmless and suitable for use in food, drugs, and cosmetics, or in drugs and cosmetics, or in externally applied drugs and cosmetics, as the case may be;

(2) A full statement of the percentages and compositions of the pure dye and all intermediates and other impurities contained in such color;

(3) A full statement showing the identity, purity, and quantity or proportion of each intermediate and other article used as a component of such color, and all steps in the process used for the manufacture of such color;

(4) A full description of practical and accurate methods of analysis for the quantitative determination of the pure dye and of all intermediates and other impurities contained in such color;

(5) A full description of practical and accurate methods for the identification of such dye in food, drugs, and cosmetics colored therewith, or in drugs and cosmetics colored therewith;

(6) A 5-pound sample of such color (unless the Food and Drug Administration authorizes or requires submission of other quantity suitable to the need for investigation) taken from a batch produced under practical manufacturing conditions, and accurately representative of such batch; and

(7) The advance deposit prescribed by § 9.15 (b) (2).

(b) If the Secretary determines, after such investigation as he considers to be necessary, that:

(1) Such color is harmless and suitable for use in foods, drugs, and cosmetics, or in drugs and cosmetics, or in externally applied drugs and cosmetics;

(2) Practical and accurate methods of analysis exists for the quantitative determination of the pure dye and all intermediates and other impurities contained in such color; and

(3) Practical and accurate methods exist for the identification of such dye in food, drugs, and cosmetics colored therewith, or in drugs and cosmetics colored therewith, the Secretary, for the purpose of listing such color in § 9.3, § 9.4, or § 9.5, shall proceed with a proposed amendment to this part as prescribed by section 701 (e) of the act.

(c) If the Secretary, after such investigation as he considers to be necessary, determines that such color does not comply with the requirements laid down by paragraph (b) of this section with respect to procedure for the purpose of listing such color in § 9.3, § 9.4, or § 9.5, the Secretary shall give notice thereof to the applicant, stating the respects in which such color does not so comply.

§ 9.15 *Fees.* (a) (1) The fee for the services provided by the regulations in this part, in the case of each request for certification submitted in accordance with § 9.8 (b), shall be 10 cents per pound of the batch covered by such request; but no such fee shall be less than $75.00.

(2) The fees for the services provided under the regulations in this part in the case of each request for certification submitted in accordance with § 9.8 (c) or (d) shall be:

Weight of batch:	*Fee*
100 pounds or less	$6.00.
Over 100 pounds but not over 500 pounds.	$6.00, plus 4 cents for each pound in excess of 100 pounds.
Over 500 pounds	$22.00, plus ½ cent for each pound in excess of 500 pounds.

(b) (1) The fee for the service provided by this part, in the case of each application for the admission of a coal-tar color in listing in § 9.3, § 9.4, or § 9.5, shall be the cost incurred by the Department in making the investigations contemplated by § 9.14 (b) and (c).

(2) Such application shall be accompanied by an advance deposit of $500 to cover such fee, and thereafter advance deposits of the same amount (unless the Food and Drug Administration authorizes deposit in other amount) shall be made whenever necessary to prevent arrears in the payment of such fee. Any excess advance deposit so made shall be returned to the applicant after the close of such investigation;

(c) All deposits and fees required by this section shall be paid by money order, bank draft, or certified check, drawn to the order of the Treasurer of the United States, collectible at par at Washington, D. C. All such deposits and fees shall be forwarded to the Food and Drug Administration, Department of Health, Education, and Welfare, Washington 25, D. C., whereupon after making appropriate records thereof they will be transmitted to the Chief Disbursing Officer, Division of Disbursement, Treasury Department, for deposit to the special account "Certification and Inspection Services, Food and Drug Administration."

(d) Whenever in the judgment of the Commissioner the ratio between fees collected (which are based upon experience and the best estimate of costs and the best estimate of earnings) and the costs of providing the service during an elapsed period of time, in the light of all circumstances and contingencies, warrants a refund from the fund collected during such period, he shall make ratable refunds to those persons to whom the services were rendered and charged, except that no refund shall be made where the computed ratable amount for the elapsed period is less than $5.00.

Subchapter B—Food and Food Products

PART 10—GENERAL REGULATIONS RELATING TO DEFINITIONS AND STANDARDS FOR FOOD

Sec.
10.1 General regulation.
10.2 General methods for water capacity and fill of containers.
10.3 General statements of substandard quality and substandard fill of container.

AUTHORITY: §§ 10.1 to 10.3, issued under sec. 701 (a), 52 Stat. 1055; 21 U. S. C. 371 (a).

§ 10.1 *General regulation.* (a) The definitions and interpretations of terms contained in section 201 of the act shall be applicable also to such terms when used in regulations promulgated under the act.

(b) If a regulation prescribing a definition and standard of identity for a food has been promulgated under section 401 of the act and the name therein specified for the food is used in any other regulation under section 401 or any other provision of the act, such name means the food which conforms to such definition and standard, except as otherwise specifically provided in such other regulation.

(c) No provision of any regulation prescribing a definition and standard of identity or standard of quality or fill of container under section 401 of the act shall be construed as in any way affecting the concurrent applicability of the general provisions of the act and the regulations thereunder relating to adulteration and misbranding. For example, all regulations under section 401 contemplate that the food and all articles used as components or ingredients thereof shall not be poisonous or deleterious and shall be clean, sound, and fit for food. A provision in such regulations for the use of coloring or flavoring does not authorize such use under circumstances or in a manner whereby damage or inferiority is concealed or whereby the food is made to appear better or of greater value than it is.

§ 10.2 *General methods for water capacity and fill of containers.* For the purposes of regulations promulgated under section 401 of the act:

(a) The term "general method for water capacity of containers" means the following method:

(1) In the case of a container with lid attached by double seam, cut out the lid without removing or altering the height of the double seam.

(2) Wash, dry, and weigh the empty container.

(3) Fill the container with distilled water at 68° Fahrenheit to 3/16 inch vertical distance below the top level of the container, and weigh the container thus filled.

(4) Subtract the weight found in subparagraph (2) from the weight found in subparagraph (3) of this paragraph. The difference shall be considered to be the weight of water required to fill the container.

In the case of a container with lid attached otherwise than by double seam, remove the lid and proceed as directed in subparagraphs (2)-(4) of this paragraph (except that under subparagraph (3) fill the container to the level of the top thereof.

(b) The term "general method for fill of containers" means the following method:

(1) In the case of a container with lid attached by double seam, cut out the lid without removing or altering the height of the double seam.

(2) Measure the vertical distance from the top level of the container to the top level of the food.

(3) Remove the food from the container; wash, dry, and weigh the container.

(4) Fill the container with water to 3/16 inch vertical distance below the top level of the container. Record the temperature of the water, weigh the container thus filled, and determine the weight of the water by substracting the weight of the container found in subparagraph (3) of this paragraph.

(5) Maintaining the water at the temperature recorded in subparagraph (4) of this paragraph, draw off water from the container as filled in subparagraph (4) to the level of the food found in subparagraph (2), weigh the container with remaining water, and determine the weight of the remaining water by subtracting the weight of the container found in subparagraph (3) of this paragraph.

(6) Divide the weight of water found in subparagraph (5) by the weight of water found in subparagraph (4), and multiply by 100. The result shall be considered to be the percent of the total capacity of the container occupied by the food.

In the case of a container with lid attached otherwise than by double seam, remove the lid and proceed as directed in subparagraphs (2)-(6) of this paragraph, except that under subparagraph (4), fill the container to the level of the top thereof.

§ 10.3 *General statements of substandard quality and substandard fill of container.* For the purposes of regulations promulgated under section 401 of the act:

(a) The term "general statement of substandard quality" means the statement "Below Standard in Quality Good Food—Not High Grade" printed in two lines of Cheltenham bold condensed caps. The words "Below Standard in Quality" constitute the first line, and the second immediately follows. If the quantity of the contents of the container is less than 1 pound, the type of the first line is 12-point, and of the second, 8-point. If such quantity is 1 pound or more, the type of the first line is 14-point, and of the second, 10-point. Such statement is enclosed within lines, not less than 6 points in width, forming a rectangle. Such statement, with enclosing lines, is on a strongly contrasting, uniform background, and is so placed as to be easily seen when the name of the food or any pictorial representation thereof is viewed, wherever such name or representation appears so conspicuously as to be easily seen under customary conditions of purchase.

(b) The term "general statement of substandard fill" means the statement "Below Standard in Fill" printed in Cheltenham bold condensed caps. If the quantity of the contents of the container is less than 1 pound, the statement is in 12-point type; if such quantity is 1 pound or more, the statement is in 14-point type. Such statement is enclosed within lines, not less than 6 points in width, forming a rectangle; but if the statement specified in paragraph (a) of this section is also used, both statements (one following the other) may be enclosed within the same rectangle. Such statement or statements, with enclosing lines, are on a strongly contrasting, uniform background, and are so placed as to be easily seen when the name of the food or any pictorial representation thereof is viewed, wherever such name or representation appears so conspicuously as to be easily seen under customary conditions of purchase.

PART 14—CACAO PRODUCTS; DEFINITIONS AND STANDARDS OF IDENTITY

Sec.
14.1 Cacao nibs, cocoa nibs, cracked cocoa; identity; label statement of optional ingredients.
14.2 Chocolate liquor, chocolate, baking chocolate, bitter chocolate, cooking chocolate, chocolate coating, bitter chocolate coating; identity; label statement of optional ingredients.
14.3 Breakfast cocoa, high fat cocoa; identity; label statement of optional ingredients.
14.4 Cocoa, medium fat cocoa; identity; label statement of optional ingredients.
14.5 Low-fat cocoa; identity; label statement of optional ingredients.
14.6 Sweet chocolate, sweet chocolate coating; identity; label statement of optional ingredients.
14.7 Milk chocolate, sweet milk chocolate, milk chocolate coating, sweet milk chocolate coating; identity; label statement of optional ingredients.
14.8 Skim milk chocolate, sweet skim milk chocolate, skim milk chocolate coating, sweet skim milk chocolate coating; identity; label statement of optional ingredients.
14.9 Buttermilk chocolate, buttermilk chocolate coating; identity; label statement of optional ingredients.
14.10 Mixed dairy product chocolates, mixed dairy product chocolate coatings; identity; label statement of optional ingredients.
14.11 Sweet chocolate and vegetable fat (other than cacao fat) coating; identity; label statement of optional ingredients.
14.12 Sweet cocoa and vegetable fat (other than cacao fat) coating; identity; label statement of optional ingredients.

AUTHORITY: §§ 14.1 to 14.12 issued under sec. 701 (a), 52 Stat. 1055; 21 U. S. C. 371 (a). Interpret or apply sec. 401, 52 Stat. 1046, 68 Stat. 54; 21 U. S. C. 341.

§ 14.1 *Cacao nibs, cocoa nibs, cracked cocoa; identity; label statement of optional ingredients.* (a) Cacao nibs, cocoa nibs, cracked cocoa is the food prepared by heating and cracking dried or cured and cleaned cacao beans and removing shell therefrom. Cacao nibs or the cacao beans from which they are prepared may be processed by heating with one or more of the following optional alkali ingredients, added as such or in aqueous solution: Bicarbonate, carbonate, or hydroxide of sodium, ammonium, or potassium; or carbonate or oxide of magnesium; but for each 100 parts by weight of cacao nibs used, as such or before shelling from the cacao beans, the total quantity of such alkalis used is not greater in neutralizing value (calculated from the respective combining weights of such alkalis used) than the neutralizing value of 3 parts by weight of anhydrous potassium carbonate. The cacao shell content of cacao nibs is not more than 1.75 percent by weight (calculated to an alkali-free basis if they or the cacao beans from which they were prepared have been processed with alkali), as determined by the method prescribed under "Shell in Cacao Nibs—Tentative" beginning on page 208 [Ed. note, 8th edition, 1955, p. 192, secs. 12.9–12.13] of "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th Ed., 1940.

(b) When cacao nibs or the cacao beans from which they are prepared are processed, in whole or in part, with any optional alkali ingredient specified in paragraph (a) of this section, the label shall bear the statement "Processed with Alkali"; but in lieu of the word "Alkali" in such statement the specific common name of the optional alkali ingredient may be used. Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, such statement shall immediately and conspicuously precede or follow such name without intervening written, printed, or graphic matter.

§ 14.2 *Chocolate liquor, chocolate, baking chocolate, bitter chocolate, cooking chocolate, chocolate coating, bitter chocolate coating; identity; label statement of optional ingredients.* (a) Chocolate liquor, chocolate, baking chocolate, bitter chocolate, cooking chocolate, chocolate coating, bitter chocolate coating is the solid or semiplastic food prepared by finely grinding cacao nibs. To such ground cacao nibs, cacao fat or a cocoa or both may be added in quantities needed to adjust the cacao fat content of the finished chocolate liquor. (For the purposes of this section the term "cocoa" means breakfast cocoa, cocoa, low-fat cocoa, or any mixture of two or more of these.) Chocolate liquor may be spiced, flavored, or otherwise seasoned with one or more of the following optional ingredients, other than any such ingredient or combinatoin of ingredients specified in subparagraphs (1), (2), or (3) of this paragraph which imparts a flavor that imitates the flavor of chocolate, milk, or butter:

(1) Ground spice.

(2) Ground vanilla beans; any natural food flavoring oil, oleoresin, or extract.

(3) Vanillin, ethyl vanillin, or other artificial food flavoring.

(4) Butter, milk fat, dried malted cereal extract, ground coffee, ground nut meats.

(5) Salt.

Any optional ingredient used with the cacao beans or cacao nibs from which such chocolate liquor is prepared, or used with any cocoa added in preparing such chocolate liquor, shall be considered to be an optional ingredient used with such chocolate liquor. The optional alkali ingredients specified for use with cacao nibs in § 14.1 (a) may be used as optional ingredients with chocolate liquor; but for each 100 parts by weight of cacao nibs used in preparing the chocolate liquor, the total quantity of such alkalis used is not greater in neutralizing value (calculated from the respective combining weights of such alkalis used) than 3 parts by weight of anhydrous potassium carbonate. The finished chocolate liquor contains not less than 50 percent and not more than 58 percent by weight of cacao fat. Unless the chocolate liquor is seasoned with butter, milk fat, or ground nut meats, the percentage of cacao fat is determined by the method prescribed under "Fat Method I—Official" beginning on page 202 [Ed. note, 8th edition, 1955, p. 198, sec. 12.22] of "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th Ed., 1940.

(b) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements prescribed in this section, showing the optional ingredients used shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

(1) When the food is seasoned with an optional ingredient specified in subparagraph (a) (1) of this section the label shall bear the statement "Spiced," "Spice Added," "With Added Spice," "Spiced With ----," or "With Added ----," the blank being filled in with the specific common name of the spice used.

(2) When the food is flavored with an optional ingredient specified in paragraph (a) (2) of this section, the label shall bear the statement "Flavored," "Flavoring Added," "With Added Flavoring," "Flavored With ------," "------ Added," or "With Added ----," the blank being filled in with the specific common name of the flavoring used.

(3) When the food is flavored with an optional ingredient specified in paragraph (a) (3) of this section, the label shall bear the statement "Artificially Flavored," "Artificial Flavoring Added," "With Artificial Flavoring," "Artificially Flavored With ----," or "With ----, an Artificial Flavoring," the blank being filled in with the specific common name of the artificial flavoring used.

(4) When the food is seasoned with an optional ingredient specified in paragraph (a) (4) of this section, the label shall bear the statement "Seasoned With ----," the blank being filled in with the specific common name of the substance used as seasoning.

(5) When any optional alkali ingredient specified in § 14.1 (a) is used, the label shall bear the statement "Processed With Alkali;" but in lieu of the word "Alkali" in such statement the specific common name of the optional alkali ingredient may be used.

Label statements prescribed in subparagraphs (1) to (4), inclusive, of this paragraph may be combined, as for example, "With Added Cinnamon, Vanilla, and Ethyl Vanillin, an Artificial Flavoring."

§ 14.3 *Breakfast cocoa, high fat cocoa; identity; label statement of optional ingredients.* (a) Breakfast cocoa, high fat cocoa is the food prepared by pulverizing the residual material remaining after part of the cacao fat has been removed from ground cacao nibs. It may be spiced, flavored, or otherwise seasoned with one or more of the following optional ingredients, other than any such ingredient or combination of ingredients which imparts a flavor that imitates the flavor of chocolate, milk, or butter:

(1) Ground spice.

(2) Ground vanilla beans; any natural food flavoring oil, oleoresin, or extract.

(3) Vanillin, ethyl vanillin, or other artificial food flavoring.

(4) Salt.

Any optional ingredient used with the cacao beans, cacao nibs, or ground cacao nibs from which such breakfast cocoa is prepared shall be considered to be an optional ingredient used with such breakfast cocoa. The optional alkali ingredients specified for use with cacao nibs in § 14.1 (a) may be used as optional ingredients with breakfast cocoa; but for each 100 parts by weight of cacao nibs used in preparing the breakfast cocoa, the total quantity of such alkalis used is not greater in neutralizing value (calculated from the respective combining weights of such alkalis used) than 3 parts by weight of anhydrous potassium carbonate. The finished breakfast cocoa contains not less than 22 percent of cacao fat, as determined by the method prescribed under "Fat Method I—Official" beginning on page 202 [Ed. note, 8th edition, 1955, p. 198, sec. 12.22] of "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th Ed., 1940.

(b) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements prescribed in this section, showing the optional ingredients used shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter:

(1) When the food is seasoned with an optional ingredient specified in paragraph (a) (1) of this section, the label shall bear the statement "Spiced," "Spice Added," "With Added Spice," "Spiced With ----," or "With Added ----," the blank being filled in with the specific common name of the spice used.

(2) When the food is flavored with an optional ingredient specified in subparagraph (a) (2) of this section, the label shall bear the statement "Flavored," "Flavoring Added," "With Added Flavoring," "Flavored With -----," "----- Added," or "With Added ----," the blank being filled in with the specific common name of the flavoring used.

(3) When the food is flavored with an optional ingredient specified in paragraph (a) (3) of this section, the label shall bear the statement "Artificially Flavored," "Artificial Flavoring Added," "With Artificial Flavoring," "Artificially Flavored With ----," or "With ----, an Artificial Flavoring," the blank being filled in with the specific common name of the artificial flavoring used.

(4) When any optional alkali ingredient specified in § 14.1 (a) is used, the label shall bear the statement "Processed With Alkali" but in lieu of the word "Alkali" in such statement the specific common name of the optional alkali ingredient may be used.

Label statements prescribed by subparagraphs (1) to (4), inclusive, of this paragraph may be combined, as for example, "With Added Cinnamon, Vanilla, and Ethyl Vanillin, an Artificial Flavoring."

§ 14.4 *Cocoa, medium fat cocoa; identity; label statement of optional ingredients.* Cocoa, medium fat cocoa conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for breakfast cocoa by § 14.3, except that it contains less than 22 percent but not less than 10 percent of cacao fat, as determined by the method referred to in § 14.3 (a).

§ 14.5 *Low-fat cocoa; identity; label statement of optional ingredients.* Low-fat cocoa conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for breakfast cocoa by § 14.3, except that it contains less than 10 percent of cacao fat as determined by the method referred to in § 14.3 (a).

§ 14.6 *Sweet chocolate, sweet chocolate coating; identity; label statement of optional ingredients.* (a) Sweet chocolate, sweet chocolate coating is the solid or semiplastic food the ingredients of which are intimately mixed and ground, prepared from chocolate liquor (with or without the addition of cacao fat) sweetened with one of the optional saccharine ingredients specified in paragraph (b) of this section. It may be spiced, flavored, or otherwise seasoned with one or more of the following optional ingredients, other than any such ingredient or combination of ingredients which imparts a flavor that imitates the flavor of chocolate, milk, or butter:

(1) Ground spice, ground vanilla beans, any natural food flavoring oil or oleoresin or extract, ground coffee, ground nut meats, honey, molasses, brown sugar, mable sugar, dried malted cereal extract, salt.

(2) Vanillin, ethyl vanillin, or other artificial food flavoring.

One or a mixture of both of the following optional emulsifying ingredients may be added in a total quantity not more than 0.5 percent of the weight of the finished food (such ingredient or mixture may be added in combination with a vegetable food fat carrier, such combination containing not less than 60 percent by weight of the emulsifying ingredient or mixture):

(3) Lecithin, with or without related natural phosphatides.

(4) Monoglycerides and diglycerides of fat-forming fatty acids in combination with monosodium phosphate derivatives thereof.

One or any mixture of two or more of the following optional dairy ingredients may be used in such quantity that the finished sweet chocolate contains less than 12 percent by weight of milk constituent solids:

(5) Butter, milk fat, cream, milk, concentrated milk, evaporated milk, sweetened condensed milk, dried milk, skim milk, concentrated skim milk, evaporated skim milk, sweetened condensed skim milk, nonfat dry milk solids, concentrated buttermilk, dried buttermilk, malted milk.

If chocolate liquor with any optional ingredient specified in § 14.2 (a) is used, such ingredient shall be considered to be an optional ingredient used with the sweet chocolate. The finished sweet chocolate contains not less than 15 percent by weight of chocolate liquor, calculated by subtracting from the weight of chocolate liquor used the weight of cacao fat therein and the weights therein of alkali and seasoning ingredients, if any, multiplying the remainder by 2.2, dividing the result by the weight of the finished sweet chocolate, and multiplying the quotient by 100. Bittersweet chocolate is sweet chocolate which contains not less than 35 percent by weight of chocolate liquor, calculated in the same manner.

(b) The optional saccharine ingredients referred to in paragraph (a) of this section are:

(1) Sugar, or partly refined cane sugar, or both.

(2) Any mixture of dextrose and sugar or partly refined cane sugar or both in which the weight of the solids of the dextrose used is not more than one-third of the total weight of the solids of all the saccharine ingredients used.

(3) Any mixture of dried corn sirup or dried glucose sirup and sugar or partly refined cane sugar or both in which the weight of the solids of the dried corn sirup or dried glucose sirup used is not more than one-fourth of the total weight of the solids of all the saccharine ingredients used.

(4) Any mixture of dextrose and dried corn sirup or dried glucose sirup and sugar or partly refined cane sugar or both in which three times the weight of the solids of the dextrose used plus four times the weight of the solids of the dried corn sirup or of the solids of the dried glucose sirup used is not more than the total weight of the solids of all the saccharine ingredients used.

(c) For the purpose of this section:

(1) The term "dextrose" means the anhydrous refined monosaccharide obtained from hydrolyzed starch.

(2) The term "dried corn sirup" means the product obtained by drying incompletely hydrolyzed cornstarch; its solids contain not less than 58 percent by weight of reducing sugars.

(3) The term "dried glucose sirup" means the product obtained by drying "glucose sirup." "Glucose sirup" is a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch. The solids of glucose sirup contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose.

(d) "Semisweet chocolate," "bittersweet chocolate," "semisweet chocolate coating," and "bittersweet chocolate coating" are alternate names for sweet chocolate which contains not less than the minimum quantity of chocolate liquor prescribed for bittersweet chocolate by paragraph (a) of this section.

(e) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements prescribed in this section, showing the optional ingredients used shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter:

(1) When the food is flavored with an optional ingredient specified in paragraph (a) (2) of this section, the label shall bear the statement "Artificially Flavored," "Artificial Flavoring Added," "With Artificial Flavoring," "Artificially Flavored With ----," or "With ----, an Artificial Flavoring," the blank being filled in with the specific common name of the artificial flavoring used.

(2) When an optional ingredient specified in paragraph (a) (3) or (4) of this section is used, the label shall bear the statement "Emulsifier Added" or "With Added Emulsifier."

(3) When any optional alkali ingredient specified in § 14.1 (a) is used the label shall bear the statement "Processed with Alkali," but in lieu of the word "Alkali" in such statement the specific common name of the optional alkali ingredient may be used.

Label statements prescribed by subparagraphs (1) and (2) of this paragraph may be combined, as for example, "With Added Emulsifier and Ethyl Vanillin, an Artificial Flavoring."

§ 14.7 *Milk chocolate, sweet milk chocolate, milk chocolate coating, sweet milk chocolate coating; identity, label statement of optional ingredients.* (a) Milk chocolate, sweet milk chocolate, milk chocolate coating, sweet milk chocolate coating is the solid or semiplastic food the ingredients of which are intimately mixed and ground, prepared from chocolate liquor (with or without the addition of cacao fat) and one or more of the optional dairy ingredients specified in paragraph (b) of this section, sweetened with one of the optional saccharine ingredients specified in § 14.6 (b) and (c). It may be spiced, flavored, or otherwise seasoned with one or more of the following optional ingredients, other than any such ingredient or combination of ingredients which imparts a flavor that imitates the flavor of chocolate, milk, or butter:

(1) Ground spice, ground vanilla beans, any natural food flavoring oil or oleoresin or extract, ground coffee, ground nut meats, honey, molasses, brown sugar, maple sugar, dried malted cereal extract, salt.

(2) Vanillin, ethyl vanillin or other artificial food flavoring.

One or a mixture of both of the following optional emulsifying ingredients may be added in a total quantity not more than 0.5 percent of the weight of the finished food (such ingredient or mixture may be added in combination with a vegetable food fat carrier, such combination containing not less than 60 percent by weight of the emulsifying ingredient or mixture):

(3) Lecithin, with or without related natural phosphatides.

(4) Monoglycerides and diglycerides of fat-forming fatty acids in combination with monosodium phosphate derivatives thereof.

If chocolate liquor with any optional ingredient specified in § 14.2 (a) is used, such ingredient shall be considered to be an optional ingredient used with the milk chocolate. The finished milk chocolate contains not less than 3.66 percent by weight of milk fat, not less than 12 percent by weight of milk solids, and not less than 10 percent by weight of chocolate liquor as calculated by subtracting from the weight of chocolate liquor used the weight of cacao fat therein and the weights therein of alkali and seasoning ingredients, if any, multiplying the remainder by 2.2, dividing the result by the weight of the finished milk chocolate, and multiplying the quotient by 100.

(b) The optional dairy ingredients referred to in paragraph (a) of this section are milk, concentrated milk, evaporated milk, sweetened condensed milk, dried milk, butter, milk fat, cream, skim milk, concentrated skim milk, evaporated skim milk, sweetened condensed skim milk, and nonfat dry milk solids; but in any such ingredient or combination of two or more of such ingredients used, the weight of nonfat milk solids is not more than 2.43 times and not less than 1.20 times the weight of milk fat therein.

(c) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements prescribed in this section, showing the optional ingredients used shall immediately and conspicuously precede or follow such name, without intervening written printed, or graphic matter:

(1) When the food is flavored with an optional ingredient specified in paragraph (a) (2) of this section, the label shall bear the statement "Artifically Flavored", "Artificial Flavoring Added", "With Artificial Flavoring", "Artifically Flavored With ------", or "With ------, an Artificial Flavoring", the blank being filled in with the specific common name of the artificial flavoring used.

(2) When an optional ingredient specified in paragraph (a) (3) or (4) of this section is used, the label shall bear the statement "Emulsifier Added" or "With Added Emulsifier."

(3) When any optional alkali ingredient specified in § 14.1 (a) is used the label shall bear the statement "Processed With Alkali", but in lieu of the word "Alkali" in such statement the specific common name of the optional alkali ingredient may be used.

Label statements prescribed by subparagraphs (1) and (2) of this paragraph may be combined, as for example, "With Added Emulsifier and Ethyl Vanillin, an Artificial Flavoring."

§ 14.8 *Skim milk chocolate, sweet skim milk chocolate, skim milk chocolate coating, sweet skim milk chocolate coating; identity; label statement of optional ingredients.* (a) Skim milk chocolate, sweet skim milk chocolate, skim milk chocolate coating, sweet skim milk chocolate coating conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for milk chocolate by § 14.7, except that:

(1) The dairy ingredients used are limited to skim milk, concentrated skim milk, evaporated skim milk, sweetened condensed skim milk, nonfat dry milk solids, and any combination of two or more of these.

(2) The finished skim milk chocolate contains less than 3.66 percent by weight of milk fat and, instead of milk solids, it contains not less than 12 percent by weight of skim milk solids.

§ 14.9 *Buttermilk chocolate, buttermilk chocolate coating; identity; label statement of optional ingredients.* (a) Buttermilk chocolate, buttermilk chocolate coating conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for milk chocolate by § 14.7, except that:

(1) The dairy ingredients used are limited to sweet cream buttermilk, concentrated sweet cream buttermilk, dried sweet cream buttermilk, or any combination of two or all of these.

(2) The finished buttermilk chocolate contains less than 3.66 percent by weight of milk fat and, instead of milk solids, it contains not less than 12 percent by weight of sweet cream buttermilk solids.

§ 14.10 *Mixed dairy product chocolates, mixed dairy product chocolate coatings; identity; label statement of optional ingredients.* (a) The articles for which definitions and standards of identity are prescribed by this section are the foods each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for milk chocolate by § 14.7, except that:

(1) The dairy ingredient used in each such article is a mixture of two or more of the following four components:

(i) Any dairy ingredient or combination of such ingredients specified in § 14.7 (b) which is within the limits of the ratios specified therein for nonfat milk solids to milk fat.

(ii) One or more of the five skim milk ingredients specified in § 14.8.

(iii) One or more of the three sweet cream buttermilk ingredients specified in § 14.9.

(iv) Malted milk.

(2) Each of the finished articles may contain less than 3.66 percent by weight of milk fat and, instead of milk solids, it contains not less than 12 percent by weight of milk constituent solids of the components used. The quantity of each component used in any such mixture is such that no component contributes less than one-third of the weight of milk constituent solids contributed by that component used in largest proportion. When any such mixture is of components (i) and (ii) of subparagraph (1), the quantity of nonfat milk solids in such mixture is more than 2.43 times the quantity of milk fat therein. For the purposes of paragraph (b) of this section, the designation of each of the components listed above is respectively "Milk," "Skim Milk," "Buttermilk," and "Malted Milk."

(b) The name of each such article is "chocolate" or "chocolate coating" preceded by the designations prescribed by paragraph (a) of this section for each component of the dairy ingredients used, such designations appearing in the order of predominance, if any, of the weight of milk constituent solids in each such component. (For example, "Milk and Skim Milk Chocolate.")

§ 14.11 *Sweet chocolate and vegetable fat (other than cacao fat) coating; identity; label statement of optional ingredients.* (a) Sweet chocolate and vegetable fat (other than cacao fat) coating conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for sweet chocolate by § 14.6, except that:

(1) In its preparation is added one or any combination of two or more vegetable food oils or vegetable food fats, other than cacao fat, which oil, fat, or combination may be hydrogenated and which has a melting point lower than that of cacao fat.

(2) The requirement of § 14.6 (a) that the milk constituent solids be less than 12 percent by weight does not apply.

(b) The provisions of this section shall not be construed as applicable to any article by reason of the addition thereto of a vegetable food fat other than cacao fat as a carrier of emulsifying ingredients, as authorized and within the limit prescribed by § 14.6 (a).

§ 14.12 *Sweet cocoa and vegetable fat (other than cacao fat) coating; identity; label statement of optional ingredients.* (a) Sweet cocoa and vegetable fat (other than cacao fat) coating conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for sweet chocolate by § 14.6, except that:

(1) In its preparation cocoa is used, instead of chocolate liquor, in such quantity that the finished food contains not less than 6.8 percent by weight of the nonfat cacao portion of such cocoa, calculated by subtracting from the weight of cocoa used the weight of cacao fat therein and the weight therein of alkali and seasoning ingredients, if any, dividing the remainder by the weight of the finished food, and multiplying the quotient by 100. (For the purposes of this section the term "cocoa" means breakfast cocoa, cocoa, low-fat cocoa, or any mixture of two or more of these.)

(2) In its preparation is added one or any combination of two or more vegetable food oils, vegetable food fats, or vegetable food stearins, other than cacao fat, which oil, fat, stearin, or combination has a melting point higher than that of cacao fat. Any such oil or fat may be hydrogenated.

(3) The requirement of § 14.6 (a) that the milk constituent solids be less than 12 percent by weight does not apply.

PART 15—CEREAL FLOURS AND RELATED PRODUCTS; DEFINITIONS AND STANDARDS OF IDENTITY

Subpart A—Wheat Flour and Related Products

Sec.
15.1 Flour, white flour, wheat flour, plain flour; identity; label statement of optional ingredients.
15.10 Enriched flour; identity; label statement of optional ingredients.
15.20 Bromated flour; identity; label statement of optional ingredients.
15.30 Enriched bromated flour; identity; label statement of optional ingredients.
15.40 Durum flour; identity.
15.50 Self-rising flour, self-rising white flour, self-rising wheat flour; identity; label statement of optional ingredients.
15.60 Enriched self-rising flour; identity; label statement of optional ingredients.
15.70 Phosphated flour, phosphated white flour, phosphated wheat flour; identity; label statement of optional ingredients.
15.80 Whole wheat flour, graham flour, entire wheat flour; identity; label statement of optional ingredients.
15.90 Bromated whole wheat flour; identity; label statement of optional ingredients.
15.100 Whole durum wheat flour; identity; label statement of optional ingredients.
15.110 Crushed wheat, coarse ground wheat; identity.
15.120 Cracked wheat; identity.
15.130 Farina; identity.
15.140 Enriched farina; identity; label statement of optional ingredients.
15.150 Semolina; identity.

Subpart B—Corn Flour and Related Products

15.500 White corn meal; identity.
15.501 Yellow corn meal; identity.
15.502 Bolted white corn meal; identity.
15.503 Bolted yellow corn meal; identity.
15.504 Degerminated white corn meal, degermed white corn meal; identity.
15.505 Degerminated yellow corn meal, degermed yellow corn meal; identity.
15.506 Self-rising white corn meal; identity.
15.507 Self-rising yellow corn meal; identity.
15.508 White corn flour; identity.
15.509 Yellow corn flour; identity.
15.510 Grits, corn grits, hominy grits; identity.
15.511 Yellow grits, yellow corn grits, yellow hominy grits; identity.
15.512 Quick grits, quick cooking grits; identity.
15.513 Enriched corn meals; identity.
15.514 Enriched corn grits; identity.

AUTHORITY: §§ 15.1 to 15.514 issued under sec. 701 (a), 52 Stat. 1055; 21 U. S. C. 371 (a). Interpret or apply sec. 401, 52 Stat. 1046, 68 Stat 54; 21 U. S. C. 341.

SUBPART A—WHEAT FLOUR AND RELATED PRODUCTS

§ 15.1 *Flour, white flour, wheat flour, plain flour; identity; label statement of optional ingredients.* (a) Flour, white flour, wheat flour, plain flour, is the food prepared by grinding and bolting cleaned wheat other than durum wheat and red durum wheat; to compensate for any natural deficiency of enzymes, malted wheat, malted wheat flour, malted barley flour, or any combination of two or more of these, may be used; but the quantity of malted barley flour so used is not more than 0.25 percent. One of the cloths through which the flour is bolted has openings not larger than those of woven wire cloth designated "149 micron (No. 100)" in Table I of "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the United States Department of Commerce, National Bureau of Standards. The flour is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis is not more than the sum of $\frac{1}{20}$ of the percent of protein therein, calculated to a moisture-free basis, and 0.35. Its moisture content is not more than 15 percent. Unless such addition conceals damage or inferiority of the flour or makes it appear better or of greater value than it is, one or any combination of two or more of the following optional bleaching ingredients may be added in a quantity not more than sufficient for bleaching or, in case such ingredient has an artificial aging effect, in a quantity not more than sufficient for bleaching and such artificial aging effect:

(1) Oxides of nitrogen.

(2) Chlorine.

(3) Nitrosyl chloride.

(4) Chlorine dioxide.

(5) One part by weight of benzoyl peroxide mixed with not more than six parts by weight of one or any mixture of two or more of the following: potassium alum, calcium sulfate, magnesium carbonate, sodium aluminum sulfate, dicalcium phosphate, tricalcium phosphate, starch, calcium carbonate.

(b) When any optional bleaching ingredient is used, the label shall bear the word "Bleached." Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the word "Bleached" shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter; except that where such name is a part of a trade-mark or brand, other written, printed, or graphic matter, which is also a part of such trade-mark or brand, may so intervene if the word "Bleached" is in such juxtaposition with such trade-mark or brand as to be conspicuously related to such name.

(c) For the purposes of this section:

(1) Ash is determined by the method prescribed in the book "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th Edition, 1940, page 212, under "Method I—Official." [Ed. note: 8th Ed., 1955, p. 207, sec. 13.6.] Ash is calculated to a moisture-free basis by subtracting the percent of moisture in the flour from 100, dividing the remainder into the percent of ash, and multiplying the quotient by 100.

(2) Protein is 5.7 times the nitrogen as determined by the method prescribed in such book on page 26, under "Kjeldahl-Gunning-Arnold Method—Official." [Ed. note: 8th Ed., 1955, p. 12 "Improved Kjeldahl method for nitrate-free samples," sec. 2.23]. Protein is calculated to a moisture-free basis by subtracting the percent of moisture in the flour from 100, dividing the remainder into the percent of protein, and multiplying the quotient by 100.

(3) Moisture is determined by the method prescribed in such book on page 211, under "Vacuum Oven Method—Official." [Ed. note: 8th Ed., 1955, p. 206, secs. 13.2, 13.3.]

§ 15.10 *Enriched flour; identity; label statement of optional ingredients.* Enriched flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for flour by § 15.1, except that:

(a) It contains in each pound not less than 2.0 milligrams and not more than 2.5 milligrams of thiamine, not less than 1.2 milligrams and not more than 1.5 milligrams of riboflavin, not less than 16.0 milligrams and not more than 20.0 milligrams of niacin or niacinamide, not less than 13.0 milligrams and not more than 16.5 milligrams of iron (Fe);

(b) Vitamin D may be added in such quantity that each pound of the finished enriched flour contains not less than 250 U. S. P. units and not more than 1,000 U. S. P. units of vitamin D;

(c) Calcium may be added in such quantity that each pound of the finished enriched flour contains not less than 500 milligrams and not more than 625 milligrams of calcium (Ca), except that enriched flour may be acidified with monocalcium phosphate irrespective of the minimum limit for calcium (Ca) prescribed in this paragraph;

(d) It may contain not more than 5 percent by weight of wheat germ or partly defatted wheat germ; and

(e) In determining whether the ash content complies with the requirements of this section allowance is made for ash resulting from any added iron or salts of iron or calcium.

Iron and calcium may be added only in forms which are harmless and assimilable. The substances referred to in paragraphs (a) and (b) of this section may be added in a harmless carrier which does not impair the enriched flour; such carrier is used only in the quantity necessary to effect an intimate and uniform admixture of such substances with the flour.

§ 15.20 *Bromated flour; identity; label statement of optional ingredients.* Bromated flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for flour by § 15.1, except that potassium bromate is added in a quantity not exceeding 50 parts to each million parts of the finished bromated flour, and is added only to flours whose baking qualities are improved by such addition.

§ 15.30 *Enriched bromated flour; identity; label statement of optional ingredients.* Enriched bromated flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for enriched flour by § 15.10, except that potassium bromate is added in a quantity not exceeding 50 parts to each million parts of the finished enriched bromated flour, and is added only to enriched flours whose baking qualities are improved by such addition.

§ 15.40 *Durum flour; identity.* (a) Durum flour is the food prepared by grinding and bolting cleaned durum wheat. One of the cloths through which such flour is bolted has openings not larger than those of woven-wire cloth designated "149 micron (No. 100)" in table I of "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the U. S. Department of Commerce, National Bureau of Standards. It is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than 1.5 percent. Its moisture content is not more than 15 percent.

(b) For the purposes of this section, ash and moisture are determined by the methods therefor referred to in § 15.1 (c).

§ 15.50 *Self-rising flour, self-rising white flour, self-rising wheat flour; identity; label statement of optional ingredients.* (a) Self-rising flour, self-rising white flour, self-rising wheat flour, is an intimate mixture of flour, sodium bicarbonate, and the acid-reacting substance monocalcium phosphate or sodium acid pyrophosphate or both. It is seasoned with salt. When it is tested by the method prescribed in paragraph (c) of this section not less than 0.5 percent of carbon dioxide is evolved. The acid-reacting substance is added in sufficient quantity to neutralize the sodium bicarbonate. The combined weight of such acid-reacting substance and sodium bicarbonate is not more than 4.5 parts to each 100 parts of flour used. Subject to the conditions and restrictions prescribed by § 15.1 (a), the bleaching ingredients specified in such section may be added as optional ingredients. If the flour used in making the self-rising flour is bleached, the optional bleaching ingredient used therein (see § 15.1 (a)) is also an optional ingredient of the self-rising flour.

(b) (1) When any optional bleaching ingredient is used, the label shall bear the word "Bleached."

(2) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the word "Bleached" shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter; except that where such name is a part of a trade-mark or brand, other written, printed, or graphic matter, which is also a part of such trade-mark or brand, may so intervene if the word "Bleached" is in such juxtaposition with such trade-mark or brand as to be conspicuously related to such name.

(c) The method referred to in paragraph (a) of this section is the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th edition, 1940, beginning on page 186 [Ed. note, 8th edition, 1955, p. 127, secs. 17.2, 17.3], under "Gasometric Method with Chittick's Apparatus—Official," except that the following procedure is substituted for the procedure specified therein under "6—Determination":

Weigh 17 grams of the official sample into flask A, add 15–20 glass beads (4–6 mm. diameter), and connect this flask with the apparatus (fig. 22). Open stopcock C and by means of the leveling bulb E bring the displacement solution to the 25 cc. graduation above the zero mark. (This 25 cc. is a partial allowance for the volume of acid to be used in the decomposition.) Allow the apparatus to stand 1–2 minutes to insure that the temperature and pressure within the apparatus are the same as those of the room. Close the stopcock, lower the leveling bulb somewhat to reduce the pressure within the apparatus, and slowly run into the decomposition flask from burette F 45 cc. of sulfuric acid (1+5). To prevent the liberated carbon dioxide from escaping through the acid burette into the air, keep the displacement solution in the leveling bulb at all times during the decomposition at a lower level than that in the gas-measuring tube. Rotate and then vigorously agitate the decomposition flask for three minutes to mix the contents intimately. Allow to stand for 10 minutes to bring to equilibrium. Equalize the pressure in the measuring tube by means of the leveling bulb and read the volume of gas from the zero point on the tube. Deduct 20 cc. from this reading (this 20 cc. together with previous allowance of 25 cc. compensates for the 45 cc. acid used in the decomposition). Observe the temperature of the air surrounding the apparatus and also the barometric pressure and multiply the number of cc. of gas evolved by the factor given in Table 24—Chapter XLIII [Ed. note, 8th edition, 1955, sec. 42.29] for the temperature and pressure observed. Divide the corrected reading by 100 to obtain the apparent percent by weight of carbon dioxide in the official sample.

Correct the apparent percent of carbon dioxide to compensate for varying atmospheric conditions by immediately assaying a synthetic sample by the same method in the same apparatus.

Prepare the synthetic sample with 16.2 grams of flour, 0.30 gram of monocalcium phosphate, 0.30 gram of salt, and a sufficient quantity of sodium bicarbonate U. S. P. (dried over sulfuric acid) to yield the amount of carbon dioxide recovered in assay of official sample. Determine this quantity by multiplying weight of carbon dioxide recovered in assay of official sample by 1.91.

Divide the weight of carbon dioxide recovered from synthetic sample by weight of carbon dioxide contained in sodium bicarbonate used.

Divide the quotient into the apparent percent of carbon dioxide in official sample to obtain percent of carbon dioxide evolved from the official sample.

§ 15.60 *Enriched self-rising flour; identity; label statement of optional ingredients.* Enriched self-rising flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for self-rising flour by § 15.50, except that:

(a) It contains in each pound not less than 2.0 milligrams and not more than 2.5 milligrams of thiamine, not less than 1.2 milligrams and not more than 1.5 milligrams of riboflavin, not less than 16.0 milligrams and not more than 20.0 milligrams of niacin or niacinamide, not less than 13.0 milligrams and not more than 16.5 milligrams of iron (Fe), not less than 500 milligrams and not more than 1,500 milligrams of calcium (Ca);

(b) Vitamin D may be added in such quantity that each pound of the finished enriched self-rising flour contains not less than 250 U. S. P. units and not more than 1,000 U. S. P. units of vitamin D;

(c) It may contain not more than 5 percent by weight of wheat germ or partly defatted wheat germ;

(d) When calcium is added as dicalcium phosphate, such dicalcium phosphate is also considered to be an acid-reacting substance; and

(e) When calcium is added as carbonate, the method set forth in § 15.50 (c) does not apply as a test for carbon dioxide evolved; but in such case the quantity of carbon dioxide evolved under ordinary conditions of use of the enriched self-rising flour is not less than 0.5 percent of the weight thereof.

Iron and calcium may be added only in forms which are harmless and assimilable. The substances referred to in paragraphs (a) and (b) of this section may be added in a harmless carrier which does not impair the enriched self-rising flour; such carrier is used only in the quantity necessary to effect an intimate and uniform admixture of such substances with the flour.

§ 15.70 *Phosphated flour, phosphated white flour, phosphated wheat flour; identity; label statement of optional ingredients.* Phosphated flour, phosphated white flour, phosphated wheat flour, conforms to the definition and standard of identity, and is subject to the requirements for label declaration of optional ingredients, prescribed for flour by § 15.1, except that:

(a) Monocalcium phosphate is added in a quantity not less than 0.25 percent and not more than 0.75 percent of the weight of the finished phosphated flour; and

(b) In determining whether the ash content complies with the requirements of this section allowance is made for the added monocalcium phosphate.

§ 15.80 *Whole wheat flour, graham flour, entire wheat flour; identity; label statement of optional ingredients.* (a) Whole wheat flour, graham flour, entire wheat flour, is the food prepared by so grinding cleaned wheat other than durum wheat and red durum wheat that, when tested by the method prescribed in paragraph (c) (2) of this section, not less than 90 percent passes through a No. 8 sieve and not less than 50 percent passes through a No. 20 sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. To compensate for any natural deficiency of enzymes, malted wheat, malted wheat flour, malted barley flour, or any combination of two or more of these, may be used; but the quantity of malted wheat flour so used is not more than 0.5 percent, and the quantity of malted barley flour so used is not more than 0.25 percent. The moisture content of whole wheat flour is not more than 15 percent. Unless such addition conceals damage or inferiority of the whole wheat flour or makes it appear better or of greater value than it is, the optional bleaching ingredient chlorine dioxide, chlorine, or a mixture of nitrosyl chloride and chlorine, may be added in a quantity not more than sufficient for bleaching and artificial aging effects.

(b) When any optional bleaching ingredient is used, the label shall bear the word "Bleached." Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the word "Bleached" shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter; except that where such name is a part of a trade-mark or brand, other written, printed, or graphic matter, which is also a part of such trade-mark or brand, may so intervene if the word "Bleached" is in such juxtaposition with such trade-mark or brand as to be conspicuously related to such name.

(c) For the purposes of this section:

(1) Moisture is determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th Edition, 1940, page 211, under "Vacuum Oven Method—Official." [Ed. note: 8th Ed., 1955, p. 206, secs. 13.2, 13.3.]

(2) The method referred to in paragraph (a) of this section is as follows: Use No. 8 and No. 20 sieves, having standard 8-inch full height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the U. S. Department of Commerce, National Bureau of Standards. Fit a No. 8 sieve into a No. 20 sieve. Attach bottom pan to the No. 20 sieve. Pour 100 gm. of the sample into the No. 8 sieve. Attach cover and hold the assembly in a slightly inclined position with one hand. Shake the sieves by striking the sides against the other hand with an upward stroke, at the rate of about 150 times per minute. Turn the sieves about one-sixth of a revolution each time in the same direction, after each 25 strokes. Continue shaking for 2 minutes. Weigh the material which fails to pass through the No. 8 sieve and the material which passes through the No. 20 sieve.

§ 15.90 *Bromated whole wheat flour; identity; label statement of optional ingredients.* Bromated whole wheat flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for whole wheat flour by § 15.80, except that potassium bromate is added in a quantity not exceeding 75 parts to each million parts of finished bromated whole wheat flour.

§ 15.100 *Whole durum wheat flour; identity; label statement of optional ingredients.* Whole durum wheat flour conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for whole wheat flour by § 15.80, except that cleaned durum wheat, instead of cleaned wheat other than durum wheat and red durum wheat, is used in its preparation.

§ 15.110 *Crushed wheat, coarse ground wheat; identity.* Crushed wheat, coarse ground wheat, is the food prepared by so crushing cleaned wheat other than durum wheat and red durum wheat that, when tested by the method prescribed in § 15.80 (c) (2), 40 percent or more passes through a No. 8 sieve and less than 50 percent passes through a No. 20 sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. Crushed wheat contains not more than 15 percent of moisture as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 5th edition, 1940, page 353 [Ed. note, 8th edition, 1955, p. 367, secs. 22.2, 22.3], under "Preparation of Sample—Official" and "Moisture I. Drying with Heat—Official."

§ 15.120 *Cracked wheat; identity.* Cracked wheat is the food prepared by so cracking or cutting into angular fragments cleaned wheat other than durum wheat and red durum wheat that, when tested by the method prescribed in § 15.80 (c) (2), not less than 90 percent passes through a No. 8 sieve and not more than 20 percent passes through a No. 20 sieve. The proportions of the natural constituents of such wheat, other than moisture, remain unaltered. Cracked wheat contains not more than 15 percent of moisture as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists", 5th edition, 1940, page 353 [Ed. note, 8th edition, 1955, p. 367, secs. 22.2, 22.3], under "Preparation of Sample—Official" and "Moisture I. Drying with Heat—Official."

§ 15.130 *Farina; identity.* (a) Farina is the food prepared by grinding and bolting cleaned wheat, other than durum wheat and red durum wheat, to such fineness that, when tested by the method prescribed in paragraph (b) (2) of this section, it passes through a No. 20 sieve, but not more than 3 percent passes through a No. 100 sieve. It is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than 0.6 percent. Its moisture content is not more than 15 percent.

(b) For the purposes of this section:

(1) Ash and moisture are determined by the methods therefor referred to in § 15.1 (c).

(2) The method referred to in paragraph (a) of this section is as follows: Use No. 20 and No. 100 sieves, having standard 8-inch full-height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the United States Department of Commerce, National Bureau of Standards. Fit a No. 20 sieve into a No. 100 sieve. Attach bottom pan to the No. 100 sieve. Pour 100 grams of the sample into the No. 20 sieve. Attach cover and hold the assembly in a slightly inclined position with one hand. Shake the sieves by striking the sides against the other hand with an upward stroke, at the rate of about 150 times per minute. Turn the sieves about one-sixth of a revolution, each time in the same direction, after each 25 strokes. Continue shaking for 2 minutes. Weigh the material which fails to pass through

the No. 20 sieve and the material which passes through the No. 100 sieve.

§ 15.140 *Enriched farina; identity; label statement of optional ingredients.* (a) Enriched farina conforms to the definition and standard of identity prescribed for farina by § 15.130, except that:

(1) It contains in each pound not less than 2.0 milligrams and not more than 2.5 milligrams of thiamine, not less than 1.2 milligrams and not more than 1.5 milligrams of riboflavin, not less than 16.0 milligrams and not more than 20.0 milligrams of niacin or niacinamide, and not less than 13.0 milligrams of iron (Fe).

(2) Vitamin D may be added in such quantity that each pound of the finished enriched farina contains not less than 250 U. S. P. units of the optional ingredient vitamin D.

(3) Calcium may be added in such quantity that each pound of the finished enriched farina contains not less than 500 milligrams of the optional ingredient calcium (Ca).

(4) It may contain not more than 8 percent by weight of the optional ingredient wheat germ or partly defatted wheat germ.

(5) It may contain not less than 0.5 percent and not more than 1 percent by weight of the optional ingredient disodium phosphate.

(6) In determining whether the ash content complies with the requirements of this section allowance is made for ash resulting from any added iron or salts of iron or calcium, or from any added disodium phosphate, or from any added wheat germ or partly defatted wheat germ.

Iron and calcium may be added only in forms which are harmless and assimilable. Dried irradiated yeast may be used as a source of vitamin D. The substances referred to in subparagraphs (1) and (2) of this paragraph may be added in a harmless carrier which does not impair the enriched farina; such carrier is used only in the quantity necessary to effect an intimate and uniform admixture of such substances with the farina.

(b) When the optional ingredient disodium phosphate is used, the label shall bear the statement "Disodium phosphate added for quick cooking." Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, such statement shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter; except that where such name is a part of trade-mark or brand, other written, printed, or graphic matter which is also a part of such trademark or brand, may so intervene if such statement is in such juxtaposition with such trademark or brand as to be conspicuously related to such name.

§ 15.150 *Semolina; identity.* (a) Semolina is the food prepared by grinding and bolting cleaned durum wheat to such fineness that, when tested by the method prescribed in § 15.130 (b) (2), it passes through a No. 20 sieve, but not more than 3 percent passes through a No. 100 sieve. It is freed from bran coat, or bran coat and germ, to such extent that the percent of ash therein, calculated to a moisture-free basis, is not more than 0.92 percent. Its moisture content is not more than 15 percent.

(b) For the purpose of this section, ash and moisture are determined by the methods therefor referred to in § 15.1 (c).

SUBPART B—CORN FLOUR AND RELATED PRODUCTS

§ 15.500 *White corn meal; identity.* (a) White corn meal is the food prepared by so grinding cleaned white corn that when tested by the method prescribed in paragraph (b) (2) of this section not less than 95 percent passes through a No. 12 sieve, not less than 45 percent through a No. 25 sieve, but not more than 35 percent through a No. 72 grits gauze. Its moisture content is not more than 15 percent. In its preparation coarse particles of the ground corn may be separated and discarded, or reground and recombined with all or part of the material from which they were separated, but in any such case the crude fiber content of the finished corn meal is not less than 1.2 percent and not more than that of the cleaned corn from which it was ground, and its fat content does not differ more than 0.3 percent from that of such corn. The contents of crude fiber and fat in all the foregoing provisions relating thereto are on a moisture-free basis.

(b) (1) For the purposes of this section moisture is determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 6th edition, page 259, sections 20.70 and 20.71 [Ed note, 8th edition, 1955, p. 220, secs. 13.54, 13.55], fat is determined by the method prescribed on pages 259 and 260, sections 20.70 and 20.73 [Ed. note, 8th edition, 1955, p. 220, secs. 13.54 and 13.59]; and crude fiber determined by the method prescribed on pages 259 and 260, sections 20.70 and 20.74 [Ed. note, 8th edition, 1955, p. 220, secs. 13.54 and 13.57].

(2) The method referred to in paragraph (a) of this section is as follows:

Use No. 12 and No. 25 sieves, having standard 8-inch diameter, full-height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the Bureau of Standards, United States Department of Commerce. A sieve with frame of the same dimensions as the Nos. 12 and 25 and fitted with 72 XXX grits gauze is used as the third sieve. It is referred to hereafter as the No. 72 sieve. The 72 XXX grits gauze has openings equivalent in size with those of No. 70 woven-wire cloth, complying with specifications for such cloth contained in such "Standard Specifications for Sieves" Attach bottom pan to No. 72 sieve. Fit the No. 25 sieve into the No. 72 sieve and the No. 12 sieve into the No. 25 sieve. Pour 100 grams of sample into the No. 12 sieve, attach cover and hold the assembly in a slightly inclined position and shake the assembly of sieves by striking the sides against one hand with an upward stroke, at the rate of about 150 times per minute. Turn the assembly of sieves about one-sixth of a revolution, each time in the same direction, after each 25 strokes. Continue shaking for 2 minutes. Weigh separately the material remaining on each sieve and in the pan, and calculate each weight as percent of sample. Sometimes when meals are tested, fine particles clog the sieve openings. If any sieve is clogged by fine material smaller than its openings, empty the contents onto a piece of paper. Remove the entrapped material on the bottom of the sieve by a hair brush and add to the sieve below. In like manner, clean the adhering material from inside the sieve and add to the material on the paper. Return mixture on the paper to the sieve, reassemble the sieves, and shake in the same manner as before for 1 minute. Repeat cleaning procedure if necessary until a 5-gram or less loss in weight occurs in any sieve during a 1-minute shaking. The percent of sample passing through No. 12 sieve shall be determined by subtracting from 100 percent, the percent of material remaining on the No. 12 sieve. The percent passing through a No. 25 sieve shall be determined by adding the percents remaining on the No. 72 sieve and the percent in pan. The percent in the pan shall be considered as the percent passing through a No. 72 XXX grits gauze.

§ 15.501 *Yellow corn meal; identity.* Yellow corn meal conforms to the definition and standard of identity prescribed by § 15.500 for white corn meal except that cleaned yellow corn is used instead of cleaned white corn.

§ 15.502 *Bolted white corn meal; identity.* (a) Bolted white corn meal is the food prepared by so grinding and sifting cleaned white corn that:

(1) Its crude fiber content is less than 1.2 percent but its fat content is not less than 2.25 percent; and

(2) When tested by the method prescribed in § 15.500 (b) (2), except that a No. 20 standard sieve is used instead of the No. 12 sieve, not less than 95 percent passes through a No. 20 sieve, not less than 45 percent through a No. 25 sieve, but not more than 25 percent through No. 72 XXX grits gauze. Its moisture content is not more than 15 percent. In its preparation particles of ground corn which contain germ may be separated, reground, and recombined with all or part of the material from which it was separated, but in any such case the fat content of the finished bolted white corn meal does not exceed by more than 0.3 percent the fat content of the cleaned corn from which it was ground. The contents of crude fiber and fat in all the foregoing provisions relating thereto are on a moisture-free basis.

(b) For the purposes of this section, moisture, fat and crude fiber are determined by the methods therefor referred to in § 15.500 (b) (1).

§ 15.503 *Bolted yellow corn meal; identity.* Bolted yellow corn meal conforms to the definition and standard of identity perscribed by § 15.502 for bolted white corn meal except that cleaned yellow corn is used instead of cleaned white corn.

§ 15.504 *Degerminated white corn meal, degermed white corn meal; identity.* (a) Degerminated white corn meal, degermed white corn meal, is the food prepared by grinding cleaned white corn and removing bran and germ so that:

(1) On a moisture-free basis, its crude fiber content is less than 1.2 percent and its fat content is less than 2.25 percent; and

(2) When tested by the method prescribed in § 15.500 (b) (2), except that a No. 20 standard sieve is used instead of a No. 12 sieve, not less than 95 percent passes through a No. 20 sieve, not less than 45 percent through a No. 25 sieve, but not more than 25 percent through No. 72 XXX grits gauze. Its moisture content is not more than 15 percent.

(b) For the purposes of this section, moisture, fat and crude fiber are determined by methods therefor referred to in § 15.500 (b) (1).

§ 15.505 *Degerminated yellow corn meal, degermed yellow corn meal; identity.* Degerminated yellow corn meal, degermed yellow corn meal, conforms to the definition and standard of identity prescribed by § 15.504 for degerminated white corn meal except that cleaned yellow corn is used instead of cleaned white corn.

§ 15.506 *Self-rising white corn meal; identity.* (a) Self-rising white corn meal is an intimate mixture of white corn meal, sodium bicarbonate, and the acid-reacting substance monocalcium phosphate. It is seasoned with salt. When it is tested by the method prescribed in paragraph (b) of this section, not less than 0.5 percent of carbon dioxide is evolved. The acid-reacting substance is added in sufficient quantity to neutralize the sodium bicarbonate. The combined weight of such acid-reacting substance and sodium bicarbonate is not more than 4.5 parts to each 100 parts of white corn meal used.

(b) The method referred to in paragraph (a) of this section is the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," 6th Edition, beginning on page 208 [Ed. note, 8th edition, 1955, p. 127, secs. 7.2, 7.3] under "Gasometric Method (2) with Chittick's Apparatus—Official," except that the following procedure is substituted for the procedure specified therein under "17.6—Determination":

Weigh 17 grams of the official sample into flask *A*, add 15–20 glass beads (4–6 mm. diameter), and connect this flask with the apparatus (fig. 25). Open stopcock *C* and by means of the leveling bulb *E* bring the displacement solution to the 25 cc. graduation above the zero mark. (This 25 cc. is a partial allowance for the volume of acid to be used in the decomposition.) Allow the apparatus to stand 1–2 minutes to insure that the temperature and pressure within the apparatus are the same as those of the room. Close the stopcock, lower the leveling bulb somewhat to reduce the pressure within the apparatus, and slowly run into the decomposition flask from burette *F* 45 cc. of sulfuric acid (1+5). To prevent the liberated carbon dioxide from escaping through the acid burette into the air, keep the displacement solution in the leveling bulb at all times during the decomposition at a lower level than that in the gas-measuring tube. Rotate and then vigorously agitate the decomposition flask for 3 minutes to mix the contents intimately. Allow to stand for 10 minutes to bring to equilibrium. Equalize the pressure in the measuring tube by means of the leveling bulb and read the volume of gas from the zero point on the tube. Deduct 20 cc. from this reading (this 20 cc. together with previous allowance of 25 cc. compensates for the 45 cc. acid used in the decomposition). Observe the temperature of the air surrounding the apparatus and also the barometric pressure and multiply the number of cc. of gas evolved by the factor given in Table 44.30 [Ed. note, 8th edition, 1955, sec. 42.29]—Reference Tables for the temperature and pressure observed. Divide the corrected reading by 100 to obtain the apparent percent by weight of carbon dioxide in the official sample.

Correct the apparent percent of carbon dioxide to compensate for varying atmospheric conditions by immediately assaying a synthetic sample by the same method in the same apparatus.

Prepare the synthetic sample with 16.2 grams of corn meal, 0.30 gram of monocalcium phosphate, 0.30 gram of salt, and a sufficient quantity of sodium bicarbonate U. S. P. (dried over sulfuric acid) to yield the amount of carbon dioxide recovered in assay of official sample. Determine this quantity by multiplying weight of carbon dioxide recovered in assay of official sample by 1.91.

Divide the weight of carbon dioxide recovered from synthetic sample by weight of carbon dioxide contained in sodium bicarbonate used.

Divide the quotient into the apparent percent of carbon dioxide in official sample to obtain percent of carbon dioxide evolved from the official sample.

§ 15.507 *Self-rising yellow corn meal; identity.* Self-rising yellow corn meal conforms to the definition and standard of identity prescribed by § 15.506 for self-rising white corn meal except that yellow corn meal is used instead of white corn meal.

§ 15.508 *White corn flour; identity.* (a) White corn flour is the food prepared by so grinding and bolting cleaned white corn that when tested by the method prescribed in paragraph (b) (2) of this section, not less than 98 percent passes through a No. 50 sieve and not less than 50 percent passes through No. 70 woven-wire cloth. Its moisture content is not more than 15 percent. In its preparation part of the ground corn may be removed, but in any such case, the content (on a moisture-free basis) of neither the crude fiber nor fat in the finished white corn flour exceeds the content (on a moisture-free basis) of such substance in the cleaned corn from which it was ground.

(b) (1) For the purpose of this section, moisture, fat, and crude fiber are determined by methods therefor referred to in § 15.500 (b) (1).

(2) The method referred to in paragraph (a) of this section is as follows: Weigh 5 grams of sample into a tared truncated metal cone (top diameter 5 centimeters, bottom diameter 2 centimeters, height 4 centimeters), fitted at bottom with 70-mesh wire cloth complying with the specifications for No. 70 wire cloth in "Standard Specifications for Sieves," published March 1, 1940 in L. C. 584 of the Bureau of Standards, United States Department of Commerce. Attach cone to a suction flask. Wash with 150 ml. of petroleum either applied in a small stream without suction, while gently stirring the sample with a small glass rod. Apply suction for 2 minutes after washing is completed, then shake the cone for 2 minutes with a vigorous horizontal motion, striking the side against the hand, and then weigh. The decrease in weight of sample, calculated as percent by weight of sample shall be considered the percent passing through No. 70 wire cloth. Transfer the residue from cone to a No. 50 sieve having a standard 8-inch diameter full-height frame, complying with the specifications for wire cloth and sieve frame in said "Standard Specifications for Sieves." Shake for 2 minutes with a vigorous horizontal motion, striking the side against the hand; remove and weigh the residue; calculate the weight of residue as percent by weight of sample, and subtract from 100 percent to obtain the percent of sample passing through the No. 50 sieve.

§ 15.509 *Yellow corn flour; identity.* Yellow corn flour conforms to the definition and standard of identity prescribed by § 15.508 for white corn flour except that cleaned yellow corn is used instead of cleaned white corn.

§ 15.510 *Grits, corn grits, hominy grits; identity.* (a) Grits, corn grits, hominy grits, is the food prepared by so grinding and sifting cleaned white corn, with removal of corn bran and germ, that:

(1) On a moisture-free basis its crude fiber content is not more than 1.2 percent and its fat content is not more than 2.25 percent; and

(2) When tested by the method prescribed in paragraph (b) (2) of this section not less than 95 percent passes through a No. 10 sieve but not more than 20 percent through a No. 25 sieve.

(b) (1) For the purposes of this section moisture, fat, and crude fiber are determined by methods therefor referred to in § 15.500 (b) (1).

(2) The method referred to in paragraph (a) of this section is as follows: Use No. 10 and No. 25 sieves, having standard 8-inch diameter full-height frames, complying with the specifications for wire cloth and sieve frames in "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the Bureau of Standards, United States Department of Commerce. Attach bottom pan to No. 25 sieve. Fit the No. 10 sieve into the No. 25 sieve. Pour 100

grams of sample into the No. 10 sieve, attach cover and hold assembly in a slightly inclined position, shake the sieves by striking the sides against one hand with an upward stroke, at the rate of about 150 times per minute. Turn the sieves about one-sixth of a revolution each time in the same direction after each 25 strokes. Continue shaking for 2 minutes. Weigh separately the material remaining on the No. 10 sieve and in the pan, and calculate each weight as percent of sample. The percent of sample passing through a No. 10 sieve shall be determined by subtracting from 100 percent the percent remaining on the No. 10 sieve. The percent of material in the pan shall be considered as the percent passing through a No. 25 sieve.

§ 15.511 *Yellow grits, yellow corn grits, yellow hominy grits; identity.* Yellow grits, yellow corn grits, yellow hominy grits, conforms to the definition and standard of identity prescribed by § 15.510 for grits except that cleaned yellow corn is used instead of cleaned white corn.

§ 15.512 *Quick grits, quick cooking grits; identity.* (a) Quick grits, quick cooking grits are the foods, each of which conforms to the definition and standard of identity prescribed for a kind of grits by §§ 15.510 or 15.511, except that in process of preparation the grits are lightly steamed and slightly compressed so as to fracture the particles.

(b) The name of each kind of grits is "Quick" or "Quick cooking" followed by the name of the kind of grits used which is prescribed in the definition and standard of identity therefor.

§ 15.513 *Enriched corn meals; identity.* (a) Enriched corn meals are the foods, each of which conforms to the definition and standard of identity prescribed for a kind of corn meal by §§ 15.500 to 15.507, inclusive, except that:

(1) It contains in each pound not less than 2.0 mg. and not more than 3.0 mg. of thiamine, not less than 1.2 mg. and not more than 1.8 mg. of riboflavin, not less than 16 mg. and not more than 24 mg. of niacin or niacinamide, and not less than 13 mg. and not more than 26 mg. of iron (Fe);

(2) It may contain in each pound not less than 250 U. S. P. units and not more than 1,000 U. S. P. units of vitamin D; and

(3) It may contain in each pound not less than 500 mg. and not more than 750 mg. of calcium (Ca). Iron and calcium may be added only in forms which are harmless and assimilable. The substances referred to in this subparagraph and in subparagraphs (1) and (2) of this paragraph may be added in a harmless carrier which does not impair the enriched corn meal; such carrier is used only in the quantity necessary to effect an intimate and uniform admixture of such substances with the kind of corn meal used. Dried yeast in quantities not exceeding 1.5 percent by weight of the finished food may be used.

(b) The name of each kind of enriched corn meal is the word "Enriched" followed by the name of the kind of corn meal used which is prescribed in the definition and standard of identity therefor.

§ 15.514 *Enriched corn grits; identity.* (a) Enriched corn grits are the foods, each of which conforms to the definition and standard of identity prescribed for grits, yellow grits, or quick cooking grits by §§ 15.510 to 15.512, inclusive, except that:

(1) It contains in each pound not less than 2.0 mg. and not more than 3.0 mg. of thiamine, not less than 1.2 mg. and not more than 1.8 mg. of riboflavin, not less than 16 mg. and not more than 24 mg. of niacin or niacinamide, not less than 13 mg. and not more than 26 mg. of iron (Fe);

(2) It may contain in each pound not less than 250 U. S. P. units and not more than 1,000 U. S. P. units of vitamin D; and

(3) It may contain in each pound not less than 500 mg. and not more than 750 mg. of calcium (Ca). Iron and calcium may be added only in forms which are harmless and assimilable. The vitamins referred to in subparagraph (1) of this paragraph may be combined with harmless substances to render them insoluble in water if the water-insoluble products are assimilable. The substances referred to in this subparagraph and in subparagraphs (1) and (2) of this paragraph may be added in a harmless carrier; such carrier is used only in the quantity necessary to effect an intimate and uniform admixture of such substances with the kind of corn grits used. Dried yeast in quantities not exceeding 1.5 percent by weight of the finished food may be used. When the finished food is tested by the method prescribed in paragraph (c) of this section it complies with the requirements set forth therein.

(b) The name of each kind of enriched corn grits is the word "Enriched" followed by the name of the kind of corn grits used which is prescribed in the definition and standard of identity therefor.

(c) The method referred to in paragraph (a) of this section is as follows: Transfer 100 grams of enriched grits to a 2-liter Erlenmeyer flask containing 1 liter of water at 25° C. Stopper the flask and rotate it for exactly ½ minute so that the grits are kept in motion. Allow the grits to settle for ½ minute, then pour off 850 cc. of the water along with any floating or suspended matter. Determine thiamine, riboflavin, niacin, and iron in the wet grits and water remaining in the flask. Calculate as mg. per pound of the grits before rinsing. The amounts found by this procedure are not less than 85 percent of the minimum amounts of thiamine, riboflavin, niacin, and iron prescribed by the standard for enriched grits.

Part 16—Alimentary Pastes; Definitions and Standards of Identity

Sec.
16.1 Macaroni products; identity; label statement of optional ingredients.
16.2 Milk macaroni products; identity; label statement of optional ingredients.
16.3 Whole wheat macaroni products; identity; label statement of optional ingredients.
16.4 Wheat and soy macaroni products; identity; label statement of optional ingredients.
16.5 Vegetable macaroni products; identity; label statement of optional ingredients.
16.6 Noodle products; identity; label statement of optional ingredients.
16.7 Wheat and soy noodle products; identity; label statement of optional ingredients.
16.8 Vegetable noodle products; identity; label statement of optional ingredients.
16.9 Enriched macaroni products; identity; label statement of optional ingredients.
16.10 Enriched noodle products; identity; label statement of optional ingredients.

AUTHORITY: §§ 16.1 to 16.10 issued under sec. 701 (a), 52 Stat. 1055; 21 U. S. C. 371 (a). Interpret or apply sec. 401, 52 Stat. 1046, 68 Stat. 54; 21 U. S. C. 341.

§ 16.1 *Macaroni products; identity; label statement of optional ingredients.* (a) Macaroni products are the class of food each of which is prepared by drying formed units of dough made from semolina, durum flour, farina, flour, or any combination of two or more of these, with water and with or without one or more of the optional ingredients specified in subparagraphs (1) to (5), inclusive, of this paragraph:

(1) Egg white, frozen egg white, dried egg white, or any two or all of these, in such quantity that the solids thereof is not less than 0.5 percent and not more than 2.0 percent of the weight of the finished food.

(2) Disodium phosphate, in a quantity not less than 0.5 percent and not more than 1.0 percent of the weight of the finished food.

(3) Onions, celery, garlic, bay leaf, or any two or more of these, in a quantity which seasons the food.

(4) Salt, in a quantity which seasons the food.

(5) Gum gluten, in such quantity that the protein content of the finished food is not more than 13 percent by weight.

The finished macaroni product contains not less than 87 percent of total solids as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fifth Edition, 1940, page 235 [Ed. note, 8th edition, 1955, p. 230, sec. 13.109], under "Vacuum Oven Method—Official."

(b) Macaroni is the macaroni product the units of which are tube-shaped and more than 0.11 inch but not more than 0.27 inch in diameter.

(c) Spaghetti is the macaroni product the units of which are tube-shaped or cord-shaped (not tubular) and more than 0.06 inch but not more than 0.11 inch in diameter.

(d) Vermicelli is the macaroni product the units of which are cord-shaped (not tubular) and not more than 0.06 inch in diameter.

(e) The name of each food for which a definition and standard of identity is prescribed by this section is "Macaroni

Product"; or alternately, the name is "Macaroni," "Spaghetti," or "Vermicelli," as the case may be, when the units of the food are of the shapes and sizes specified in paragraph (b), (c), or (d), respectively, of this section.

(f) (1) When disodium phosphate is used the label shall bear the statement "Disodium phosphate added for quick cooking."

(2) When any ingredient specified in paragraph (a) (3) of this section is used the label shall bear the statement "Seasoned with______," the blank being filled in with the common name of the ingredient; or in the case of bay leaves the statement "Spiced," "Spice added," or "Spiced with bay leaves."

(3) Wherever the name of the food appears on such label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed in this section, showing the optional ingredients used shall immediately and conspicuously precede or follow, or in part precede and in part follow, such name without intervening written, printed, or other graphic matter.

§ 16.2 *Milk macaroni products; identity; label statement of optional ingredients.* (a) Milk macaroni products are the class of food each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for macaroni products by § 16.1 (a) and (f) (2) and (3), except that:

(1) Milk is used as the sole moistening ingredient in preparing the dough; or in lieu of milk one or more of the milk ingredients specified in paragraph (f) of this section is used, with or without water, in such quantity that the weight of milk solids therein is not less than 3.8 percent of the weight of the finished milk macaroni product; and

(2) None of the optional ingredients permitted by § 16.1 (a) (1) and (2) is used. When the optional ingredient gum gluten (§ 16.1 (a) (5)) is added, the quantity is such that the protein derived therefrom, together with the protein derived from semolina, durum flour, farina, flour, or any combination of these used, does not exceed 13 percent of the weight of the finished food.

(b) Milk macaroni is the milk macaroni product the units of which conform to the specifications of shape and size prescribed for macaroni by § 16.1 (b).

(c) Milk spaghetti is the milk macaroni product the units of which conform to the specifications of shape and size prescribed for spaghetti by § 16.1 (c).

(d) Milk vermicelli is the milk macaroni product the units of which conform to the specifications of shape and size prescribed for vermicelli by § 16.1 (d).

(e) The name of each food for which a definition and standard of identity is prescribed by this section is "Milk Macaroni Product"; or alternatively, the name is "Milk Macaroni," "Milk Spaghetti," or "Milk Vermicelli," as the case may be, when the units of the food comply with the requirements of paragraph (b), (c), or (d), respectively, of this section.

(f) The milk ingredients referred to in paragraph (a) (1) of this section are concentrated milk, evaporated milk, dried milk, and a mixture of butter with skim milk, concentrated skim milk, evaporated skim milk, defatted milk solids (dried skim milk), or any two or more of these, in such proportion that the weight of nonfat milk solids in such mixture is not more than 2.275 times the weight of milk fat therein.

§ 16.3 *Whole wheat macaroni products; identity; label statement of optional ingredients.* (a) Whole wheat macaroni products are the class of food each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for macaroni products by § 16.1 (a) and (f) (2) and (3), except that:

(1) Whole wheat flour or whole durum wheat flour or both are used as the sole wheat ingredient; and

(2) None of the optional ingredients permitted by § 16.1 (a) (1), (2), and (5) is used.

(b) Whole wheat macaroni is the whole wheat macaroni product the units of which conform to the specifications of shape and size prescribed for macaroni by § 16.1 (b).

(c) Whole wheat spaghetti is the whole wheat macaroni product the units of which conform to the specifications of shape and size prescribed for spaghetti by § 16.1 (c).

(d) Whole wheat vermicelli is the whole wheat macaroni product the units of which conform to the specifications of shape and size prescribed for vermicelli by § 16.1 (d).

(e) The name of each food for which a definition and standard of identity is prescribed by this section is "Whole Wheat Macaroni Product"; or alternatively, the name is "Whole Wheat Macaroni," "Whole Wheat Spaghetti," or "Whole Wheat Vermicelli," as the case may be, when the units of the food comply with the requirements of paragraph (b), (c), or (d), respectively, of this section.

§ 16.4 *Wheat and soy macaroni products; identity; label statement of optional ingredients.* (a) Wheat and soy macaroni products are the class of food each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for macaroni products by § 16.1 (a) and (f) (2) and (3), except that:

(1) Soy flour is added in a quantity not less than 12.5 percent of the combined weight of the wheat and soy ingredients used (the soy flour used is made from heat-processed, dehulled soybeans, with or without the removal of fat therefrom); and

(2) None of the optional ingredients permitted by § 16.1 (a) (1) and (2) is used. When the optional ingredient gum gluten (§ 16.1 (a) (5)) is added, the quantity is such that the protein derived therefrom, together with the protein derived from semolina, durum flour, farina, flour or any combination of these used, does not exceed 13 percent of the weight of the finished food.

(b) Wheat and soy macaroni is the wheat and soy macaroni product the units of which conform to the specifications of shape and size prescribed for macaroni by § 16.1 (b).

(c) Wheat and soy spaghetti is the wheat and soy macaroni product the units of which conform to the specifications of shape and size prescribed for spaghetti by § 16.1 (c).

(d) Wheat and soy vermicelli is the wheat and soy macaroni product the units of which conform to the specifications of shape and size prescribed for vermicelli by § 16.1 (d).

(e) The name of each food for which a definition and standard of identity is prescribed by this section is "Wheat and Soy Macaroni Product," "Wheat and Soybean Macaroni Product," "________ and Soy Macaroni Product," or "_______ and Soybean Macaroni Product," the blank in each instance being filled in with the name whereby the wheat ingredient used is designated in § 16.1 (a); or alternatively, the name is "Wheat and Soy Macaroni," "Wheat and Soybean Macaroni," "______ and Soy Macaroni," or "______ and Soybean Macaroni" when the units of the food comply with the requirements of paragraph (b) of this section; or "Wheat and Soy Spaghetti," "Wheat and Soybean Spaghetti," "______ and Soy Spaghetti," or "________ and Soybean Spaghetti" when such units comply with the requirements of paragraph (c) of this section; or "Wheat and Soy Vermicelli," "Wheat and Soybean Vermicelli," "________ and Soy Vermicelli," or "______ and Soybean Vermicelli" when such units comply with the requirements of paragraph (d) of this section, the blank in each instance being filled in with the name whereby the wheat ingredient used is designated in § 16.1 (a).

§ 16.5 *Vegetable macaroni products; identity; label statement of optional ingredients.* (a) Vegetable macaroni products are the class of food each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for macaroni products by § 16.1 (a) and (f) (2) and (3), except that:

(1) Tomato (of any red variety), artichoke, beet, carrot, parsley, or spinach is added in such quantity that the solids thereof is not less than 3 percent by weight of the finished vegetable macaroni product (the vegetable used may be fresh, canned, dried, or in the form of puree or paste); and

(2) None of the optional ingredients permitted by § 16.1 (a) (1) and (2) is used. When the optional ingredient gum gluten (§16.1 (a) (5)) is added, the quantity is such that the protein derived therefrom, together with the protein derived from the semolina, durum flour, farina, flour or any combination of these used, does not exceed 13 percent of the weight of the finished food.

(b) Vegetable macaroni is the vegetable macaroni product the units of which conform to the specifications of shape and size prescribed for macaroni by § 16.1 (b).

(c) Vegetable spaghetti is the vegetable macaroni product the units of which conform to the specifications of shape and size prescribed for spaghetti by § 16.1 (c).

(d) Vegetable vermicelli is the vegetable macaroni product, the units of which conform to the specifications of shape and size prescribed for vermicelli by § 16.1 (d).

(e) The name of each food for which a definition and standard of identity is prescribed by this section is "------ Macaroni Product," the blank being filled in with the name whereby the vegetable used is designated in paragraph (a) of this section; or alternatively, the name is "------ Macaroni," "------ Spaghetti," or "------ Vermicelli," as the case may be, when the units of the food comply with the requirements of paragraph (b), (c), or (d), respectively, the blank in each instance being filled in with the name whereby the vegetable used is designated in paragraph (a) of this section.

§ 16.6 *Noodle products; identity; label statement of optional ingredients.* (a) Noodle products are the class of food each of which is prepared by drying formed units of dough made from semolina, durum flour, farina, flour, or any combination of two or more of these, with liquid eggs, frozen eggs, dried eggs, egg yolks, frozen yolks, dried yolks, or any combination of two or more of these, with or without water and with or without one or more of the optional ingredients specified in subparagraphs (1) to (3), inclusive:

(1) Onions, celery, garlic, bay leaf, or any two or more of these, in a quantity which seasons the food.

(2) Salt, in a quantity which seasons the food.

(3) Gum gluten, in such quantity that the protein derived therefrom, together with the protein derived from semolina, durum flour, farina, flour or any combination of these used, does not exceed 13 percent of the weight of the finished food.

The finished noodle product contains not less than 87 percent of total solids as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fifth Edition, 1940, page 235 [Ed. note, 8th edition, 1955, p. 230, sec. 13.109], under "Vacuum Oven Method—Official." The total solids of noodle products contains not less than 5.5 percent by weight of the solids of egg, or egg yolk.

(b) Noodles, egg noodles, is the noodle product the units of which are ribbon-shaped.

(c) Egg macaroni is the noodle product the units of which are tube-shaped and more than 0.11 inch but not more than 0.27 inch in diameter.

(d) Egg spaghetti is the noodle product the units of which are tube-shaped or cord-shaped (not tubular) and more than 0.06 inch but not more than 0.11 inch in diameter.

(e) Egg vermicelli is the noodle product the units of which are cord-shaped (not tubular) and not more than 0.06 inch in diameter.

(f) The name of each food for which a definition and standard of identity is prescribed by this section is "Noodle Product" or "Egg Noodle Product"; or alternatively, the name is "Noodles" or "Egg Noodles," "Egg Macaroni," "Egg Spaghetti," or "Egg Vermicelli," as the case may be, when the units of the food are of the shapes and sizes specified in paragraph (b), (c), (d), or (e), respectively, of this section.

(g) When any ingredient specified in paragraph (a) (1) of this section is used, the label of the noodle product shall bear the statement "Seasoned with --------," the blank being filled in with the common name of the ingredient; or in the case of bay leaves the statement "Spiced," "Spice added," or "Spiced with bay leaves."

(h) Wherever the name of the food appears on such label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed in this section, showing the ingredients used shall immediately and conspicuously precede or follow, or in part precede and in part follow, such name without intervening written, printed, or other graphic matter.

§ 16.7 *Wheat and soy noodle products; identity; label statement of optional ingredients.* (a) Wheat and soy noodle products are the class of food each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for noodle products by § 16.6 (a) and (g), except that soy flour is added in a quantity not less than 12.5 percent of the combined weight of the wheat and soy ingredients used (the soy flour used is made from heat-processed, dehulled soybeans, with or without the removal of fat therefrom).

(b) Wheat and soy noodles, wheat and soy egg noodles, is the wheat and soy noodle product the units of which are ribbon-shaped.

(c) Wheat and soy egg macaroni is the wheat and soy noodle product the units of which conform to the specifications of shape and size prescribed for egg macaroni by § 16.6 (c).

(d) Wheat and soy egg spaghetti is the wheat and soy noodle product the units of which conform to the specifications of shape and size prescribed for egg spaghetti by § 16.6 (d).

(e) Wheat and soy egg vermicelli is the wheat and soy noodle product the units of which conform to the specifications of shape and size prescribed for egg vermicelli by § 16.6 (e).

(f) The name of each food for which a definition and standard of identity is prescribed by this section is "Wheat and Soy Noodle Product," "Wheat and Soy Egg Noodle Product," "Wheat and Soybean Noodle Product," "Wheat and Soybean Egg Noodle Product," "------ and Soy Noodle Product," "------ and Soy Egg Noodle Product," "------ and Soybean Noodle Product," or "------ and Soybean Egg Noodle Product," the blank in each instance being filled in with the name whereby the wheat ingredient used is designated in § 16.6 (a); or alternatively, the name is "Wheat and Soy Noodles," "Wheat and Soy Egg Noodles," "Wheat and Soybean Noodles," "Wheat and Soybean Egg Noodles," "------ and Soy Noodles," "------ and Soy Egg Noodles," "------ and Soybean Noodles," or "------ and Soybean Egg Noodles" when the units of the food comply with the requirements of paragraph (b) of this section; or "Wheat and Soy Egg Macaroni," "Wheat and Soybean Egg Macaroni," "------ and Soy Egg Macaroni," or "------ and Soybean Egg Macaroni" when such units comply with the requirements of paragraph (c) of this section; or "Wheat and Soy Egg Spaghetti," "Wheat and Soybean Egg Spaghetti," "------ and Soy Egg Spaghetti," or "------ and Soybean Egg Spaghetti" when such units comply with the requirements of paragraph (d) of this section; or "Wheat and Soy Egg Vermicelli," "Wheat and Soybean Egg Vermicelli," "------ and Soy Egg Vermicelli," or "------ and Soybean Egg Vermicelli," when such units comply with the requirements of paragraph (e) of this section, the blank in each instance being filled in with the name whereby the wheat ingredient used is designated in § 16.6 (a).

§ 16.8 *Vegetable noodle products; identity; label statement of optional ingredients.* (a) Vegetable noodle products are the class of food each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for noodle products by § 16.6 (a) and (g), except that tomato (of any red variety), artichoke, beet, carrot, parsley, or spinach is added in such quantity that the solids thereof is not less than 3 percent by weight of the finished vegetable noodle product (the vegetable used may be fresh, canned, dried, or in the form of puree or paste).

(b) Vegetable noodles, vegetable egg noodles, is the vegetable noodle product the units of which are ribbon-shaped.

(c) Vegetable egg macaroni is the vegtable noodle product the units of which conform to the specifications of shape and size prescribed for egg macaroni by § 16.6 (c).

(d) Vegetable egg spaghetti is the vegetable noodle product the units of which conform to the specifications of shape and size prescribed for egg spaghetti by § 16.6 (d).

(e) Vegetable egg vermicelli is the vegetable noodle product the units of which conform to the specifications of shape and size prescribed for egg vermicelli by § 16.6 (e).

(f) The name of each food for which a definition and standard of identity is prescribed by this section is "---------- Noodle Product" or "------ Egg Noodle Product," the blank being filled in with the name whereby the vegetable used is designated in paragraph (a) of this section; or alternatively, the name is "----- Noodles" or "------ Egg Noodles," "------- Egg Macaroni," "------- Egg Spaghetti," or "------ Egg Vermicelli," as the case may be, when the units of the food comply with the requirements of paragraph (b), (c), (d), or (e), respectively, the blank in each instance being filled in with the name whereby the vegetable is designated in paragraph (a) of this section.

§ 16.9 *Enriched macaroni products; identity; label statement of optional ingredients.* (a) Enriched macaroni products are the class of food each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for macaroni products by § 16.1 (a) and (f), except that:

(1) Each such food contains in each pound not less than 4 mg. and not more than 5 mg. of thiamine, not less than 1.7 mg. and not more than 2.2 mg. of riboflavin, not less than 27 mg. and not more than 34 mg. of niacin or niacinamide, and not less than 13 mg. and not more than 16.5 mg. of iron (Fe);

(2) Each such food may also contain as an optional ingredient added vitamin D in such quantity that each pound of the finished food contains not less than 250 U. S. P. units and not more than 1000 U. S. P. units of vitamin D;

(3) Each such food may also contain as an optional ingredient added calcium in such quantity that each pound of the finished food contains not less than 500 mg. and not more than 625 mg. of calcium (Ca);

(4) Each such food may also contain as an optional ingredient partly defatted wheat germ but the amount thereof does not exceed 5 percent of the weight of the finished food;

(5) Each such food may be supplied, wholly or in part, with the prescribed quantity of any substance referred to in subparagraphs (1), (2), and (3) of this paragraph through the use of dried yeast, partly defatted wheat germ, enriched farina or enriched flour, or through the direct additions of any of the substances prescribed in subparagraphs (1), and (2), and (3).

Iron and calcium may be added only in forms which are harmless and assimilable. The substances referred to in subparagraphs (1) and (2) of this paragraph may be added in a harmless carrier which does not impair the enriched macaroni product, such carrier being used only in the quantity reasonably necessary to effect an intimate and uniform distribution of such substances in the finished enriched macaroni product.

(b) Enriched macaroni is the enriched macaroni product the units of which conform to the specifications of shape and size prescribed for macaroni by § 16.1 (b).

(c) Enriched spaghetti is the enriched macaroni product the units of which conform to the specifications of shape and size prescribed for spaghetti by § 16.1 (c).

(d) Enriched vermicelli is the enriched macaroni product the units of which conform to the specifications of shape and size prescribed for vermicelli by § 16.1 (d).

(e) The name of each food for which a definition and standard of identity is prescribed by this section is "Enriched Macaroni Product"; or alternatively, the name is "Enriched Macaroni," "Enriched Spaghetti," or "Enriched Vermicelli," as the case may be, when the units of the food comply with the requirements of paragraphs (b), (c), or (d) respectively of this section.

§ 16.10 *Enriched noodle products; identity; label statement of optional ingredients.* (a) Enriched noodle products are the class of food each of which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for noodle products by § 16.6 (a) and (g), except that:

(1) Each such food contains in each pound not less than 4 mg. and not more than 5 mg. of thiamine, not less than 1.7 mg. and not more than 2.2 mg. of riboflavin, not less than 27 mg. and not more than 34 mg. of niacin or niacinamide, and not less than 13 mg. and not more than 16.5 mg. of iron (Fe);

(2) Each such food may also contain as an optional ingredient added vitamin D in such quantity that each pound of the finished food contains not less than 250 U. S. P. units and not more than 1000 U. S. P. units of vitamin D;

(3) Each such food may also contain as an optional ingredient added calcium in such quantity that each pound of the finished food contains not less than 500 mg. and not more than 625 mg. of calcium (Ca);

(4) Each such food may also contain as an optional ingredient partly defatted wheat germ, but the amount thereof does not exceed 5 percent of the weight of the finished food;

(5) Each such food may be supplied, wholly or in part, with the prescribed quantity of any substance referred to in subparagraphs (1), (2), and (3), of this paragraph through the use of dried yeast, partly defatted wheat germ, enriched farina or enriched flour, or through the direct additions of any of the substances prescribed in subparagraphs (1), (2), and (3).

Iron and calcium may be added only in forms which are harmless and assimilable. The substances referred to in subparagraphs (1) and (2) of this paragraph may be added in a harmless carrier which does not impair the enriched noodle product, such carrier being used only in the quantity reasonably necessary to effect an intimate and uniform distribution of such substances in the finished enriched noodle product.

(b) Enriched noodles, enriched egg noodles are the enriched noodle products the units of which conform to the specifications of shape and size prescribed for noodles in § 16.6 (b).

(c) Enriched egg macaroni is the enriched noodle product the units of which conform to the specifications of shape and size prescribed for egg macaroni in § 16.6 (c).

(d) Enriched egg spaghetti is the enriched noodle product the units of which conform to the specifications of shape and size prescribed for egg spaghetti in § 16.6 (d).

(e) Enriched egg vermicelli is the enriched noodle product the units of which conform to the specifications of shape and size prescribed for egg vermicelli in § 16.6 (e).

(f) The name of each food for which a definition and standard of identity is prescribed by this section is "Enriched Noodle Product" or "Enriched Egg Noodle Product"; or alternatively, the name is "Enriched Noodles," or "Enriched Egg Noodles," "Enriched Egg Macaroni," "Enriched Egg Spaghetti," or "Enriched Egg Vermicelli," as the case may be, when the units of the food comply with the requirements of paragraphs (b), (c), (d), or (e) respectively of this section.

PART 17—BAKERY PRODUCTS; DEFINITIONS AND STANDARDS OF IDENTITY

Sec.

17.1 Bread, white bread, and rolls, white rolls, or buns, white buns; identity; label statement of optional ingredients.
17.2 Enriched bread and enriched rolls or enriched buns; identity; label statement of optional ingredients.
17.3 Milk bread and milk rolls or milk buns; identity; label statement of optional ingredients.
17.4 Raisin bread and raisin rolls or raisin buns; identity; label statement of optional ingredients.
17.5 Whole wheat bread, graham bread, entire wheat bread, and whole wheat rolls, graham rolls, entire wheat rolls, or whole wheat buns, graham buns, entire wheat buns; identity; label statement of optional ingredients.

AUTHORITY: §§ 17.1 to 17.5 issued under 52 Stat. 1043, 1055, 68 Stat. 54; 21 U. S. C. 341, 371.

§ 17.1 *Bread, white bread, and rolls, white rolls, or buns, white buns; identity; label statement of optional ingredients.* (a) Each of the foods bread, white bread, rolls, white rolls, buns, white buns is prepared by baking a kneaded yeast-leavened dough, made by moistening flour with water or with one or more of the optional liquid ingredients specified in this section or with any mixture of water and one or more of such ingredients. The term "flour," unqualified, as used in this section, includes flour, bromated flour, and phosphated flour. The potassium bromate in any bromated flour used and the monocalcium phosphate in any phosphated flour used shall be deemed to be optional ingredients in the bread or rolls. Each of such foods is seasoned with salt, and in its preparation one or more of the optional ingredients prescribed by subparagraphs (1) to (14), inclusive, of this paragraph may be used:

(1) Shortening, in which or in conjunction with which may be used lecithin, mono- and diglycerides of fat-forming fatty acids (except lauric acid), or diacetyl tartaric acid esters of mono- and diglycerides of fat-forming fatty acids (except lauric acid), or a combination of two or more of these. The total weight of mono- and diglycerides, including diacetyl tartaric acid esters of mono- and diglycerides of fat-forming fatty acids, used does not exceed 20 percent by weight of the combination of such a preparation and the shortening, and the total amount of monoglyceride in such mixture does not exceed 8 percent by weight of the combination; but if purified or concentrated monoglyceride is used the amount of such a preparation does not exceed 10 percent by weight of

the combination of such preparation and the shortening. For the purposes of this section the lecithin may include related phosphatides derived from the corn or soya-bean oil from which the lecithin was obtained.

(2) Milk, concentrated milk, evaporated milk, sweetened condensed milk, dried milk, skim milk, concentrated skim milk, evaporated skim milk, sweetened condensed partly skimmed milk, sweetened condensed skim milk, nonfat dry milk solids, or any combination of two or more of these; except that any such ingredient or combination, together with any butter and cream used, is so limited in quantity or composition as not to meet the requirements for milk or dairy ingredients prescribed for milk bread by § 17.3.

(3) Buttermilk, concentrated buttermilk, dried buttermilk, sweet cream buttermilk, concentrated sweet cream buttermilk, dried sweet cream buttermilk, cheese whey, concentrated cheese whey, dried cheese whey, milk proteins, or any combination of two or more of these.

(4) Liquid eggs, frozen eggs, dried eggs, egg yolks, frozen egg yolks, dried yolks, egg white, frozen egg white, dried egg white, or any combination of two or more of these.

(5) Sugar, invert sugar (in congealed or sirup form), light-colored brown sugar, refiner's sirup, dextrose, honey, corn sirup, glucose sirup, dried corn sirup, dried glucose sirup, nondiastatic malt sirup, nondiastatic dried malt sirup, molasses (except blackstrap molasses), or any combination of two or more of these.

(6) Malt sirup, dried malt sirup, malted barley flour, malted wheat flour, each of which is diastatically active; harmless preparations of enzymes obtained from Aspergillus oryzae, or any combination of two or more of these.

(7) Inactive dried yeast of the genus Saccharomyces cerevisiae; but the total quantity thereof is not more than 2 parts for each 100 parts by weight of flour used.

(8) Harmless lactic-acid producing bacteria.

(9) Corn flour (including finely ground corn meal), potato flour, rice flour, wheat starch, cornstarch, milo starch, potato starch, sweet potato starch (any of which may be wholly or in part dextrinized), dextrinized wheat flour, soy flour, or any combination of two or more of these; but the total quantity thereof is not more than 3 parts for each 100 parts by weight of flour used.

(10) Ground dehulled soybeans, which may be heat-treated and from which oil may be removed, but which retain enzymatic activity; but the quantity thereof is not more than 0.5 part for each 100 parts by weight of flour used.

(11) Calcium sulfate, calcium lactate, calcium carbonate, dicalcium phosphate, ammonium phosphates, ammonium sulfate, ammonium chloride, or any combination of two or more of these; but the total quantity of such ingredients is not more than 0.25 part for each 100 parts by weight of flour used.

(12) Potassium bromate, potassium iodate, calcium peroxide, or any combination of two or more of these; but the total quantity thereof (including the potassium bromate in any bromated flour used) is not more than 0.0075 part for each 100 parts by weight of flour used.

(13) (i) Monocalcium phosphate, but the total quantity thereof, including the quantity in any phosphated flour used and any quantity added, is not more than 0.75 part by weight for each 100 parts by weight of flour used.

(ii) A vinegar, in a quantity equivalent in acid strength to not more than 1 pint of 100-grain distilled vinegar for each 100 pounds of flour used; or

(iii) Calcium propionate, sodium propionate, or any mixture of these, but the total quantity thereof is not more than 0.32 part for each 100 parts by weight of flour used; or

(iv) Sodium diacetate, but the quantity thereof is not more than 0.4 part for each 100 parts by weight of flour used; or

(v) Lactic acid, in such quantity that the pH of the finished bread is not less than 4.5.

(14) Spice, with which may be included spice oil and spice extract.

Each of such foods contains not less than 62 percent of total solids, as determined by the method prescribed in "Official Methods of Analysis of the Association of Official Agricultural Chemists," Seventh Edition, 1950, page 209, section 13.70, under "Total Solids in an Entire Loaf of Bread," [Ed. note, 8th Ed., 1955, p. 222, sec. 13.72], except that if the baked unit weighs 1 pound or more one entire unit is used for the determination, and if the baked unit weighs less than 1 pound, such number of entire units as weigh 1 pound or more is used for the determination.

(b) Bread, white bread is baked in units each of which weighs one-half pound or more after cooling. Rolls, white rolls, and buns, white buns are baked in units each of which weighs less than one-half pound after cooling.

(c) (1) When any optional ingredient permitted by paragraph (a) (13) of this section is used, except a vinegar and except monocalcium phosphate, in a quantity less than 0.25 part for each 100 parts by weight of flour, the label shall bear the statement "________ added to retard spoilage," the blank being filled in with the name by which the ingredient used is designated in such paragraph.

(2) When an optional ingredient permitted by paragraph (a) (14) of this section is used, the label shall bear the statement "spiced" or "spice added" or "with added spice"; but in lieu of the word "spice" in such statements, the common or usual name of the spice may be used.

(3) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements specified in this paragraph shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 17.2 *Enriched bread and enriched rolls or enriched buns; identity; label statement of optional ingredients.* (a) Each of the foods enriched bread, enriched rolls, enriched buns conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for bread by § 17.1 (a) and (c), except that:

(1) Each such food contains in each pound not less than 1.1 milligrams and not more than 1.8 milligrams of thiamine, not less than 0.7 milligram and not more than 1.6 milligrams of riboflavin, not less than 10.0 milligrams and not more than 15.0 milligrams of niacin or niacinamide, and not less than 8.0 milligrams and not more than 12.5 milligrams of iron (Fe).

(2) Each such food may also contain as an optional ingredient added vitamin D in such quantity that each pound of the finished food contains not less than 150 United States Pharmacopeia units and not more than 750 United States Pharmacopeia units of vitamin D.

(3) Each such food may also contain as an optional ingredient added harmless calcium salts in such quantity that each pound of the finished food contains not less than 300 milligrams and not more than 800 milligrams of calcium (Ca).

(4) Each such food may also contain as an optional ingredient wheat germ or partly defatted wheat germ; but the total quantity thereof, including any wheat germ or partly defatted wheat germ in any enriched flour used, is not more than 5 percent of the flour ingredient.

(5) Enriched flour may be used, in whole or in part, instead of flour.

(6) The limitation prescribed by § 17.1 (a) (2) on the quantity and composition of milk and dairy ingredients does not apply.

As used in this section, the term "flour," unqualified, includes bromated flour and phosphated flour; the term "enriched flour" includes enriched bromated flour. The prescribed quantity of any substance referred to in subparagraphs (1), (2), and (3) of this paragraph may be supplied, or partly supplied, through the use of enriched flour; through the direct addition of such substance under the conditions permitted by § 15.10 of this chapter for supplying such substance in the preparation of enriched flour; through the use of any ingredient containing such substance, which ingredient is required or permitted by § 17.1 (a) within the limits, if any, prescribed by such section, as modified by subparagraph (6) of this paragraph; through the use of wheat germ; or through any two or more of such methods.

(b) Enriched bread is baked in units each of which weighs one-half pound or more after cooling. Enriched rolls or enriched buns are baked in units each of which weighs less than one-half pound after cooling.

§ 17.3 *Milk bread and milk rolls or milk buns; identity; label statement of optional ingredients.* (a) Each of the foods milk bread, milk rolls, milk buns conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for bread and rolls by buns by § 17.1 (a) and (c), except that:

(1) Milk is used as the sole moistening ingredient in preparing the dough; or in lieu of milk one or more of the dairy ingredients prescribed in paragraph (c) of this section is used, with or without water, in a quantity containing not less than 8.2 parts by weight of milk solids for each 100 parts by weight of flour used (including any bromated flour or phosphated flour used).

(2) No ingredient permitted by § 17.1 (a) (3) is used.

(b) Milk bread is baked in units each of which weighs one-half pound or more after cooling. Milk rolls or milk buns are baked in units each of which weighs less than one-half pound after cooling.

(c) The dairy ingredients referred to in paragraph (a) (1) of this section are concentrated milk, evaporated milk, sweetened condensed milk, dried milk, and a mixture of butter or cream or both with skim milk, concentrated skim milk, evaporated skim milk, sweetened condensed skim milk, sweetened condensed partly skimmed milk, nonfat dry milk solids, or any two or more of these, in such proportion that the weight of nonfat milk solids in such mixture is not more than 2.3 times and not less than 1.2 times the weight of the milk fat therein.

§ 17.4 *Raisin bread and raisin rolls or raisin buns; identity; label statement of optional ingredients.* (a) Each of the foods raisin bread, raisin rolls, raisin buns conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for bread and rolls or buns by § 17.1 (a) and (c), except that:

(1) Not less than 50 parts by weight of seeded or seedless raisins are used for each 100 parts by weight of flour used (including any bromated flour or phosphated flour used).

(2) Water extract of raisins may be used, but not to replace raisins.

(3) The baked units may bear icing or frosting.

(4) The limitation prescribed by § 17.1 (a) (2) on the quantity and composition of dairy ingredients does not apply.

(5) In determining its total solids, instead of following the direction "Grind sample just to pass 20-mesh sieve" (Official Methods of Analysis of the Association of Official Agricultural Chemists, Seventh Edition, 1950, page 209, section 13.70 [Ed. Note, 8th Ed., 1955, p. 222, sec. 13.72], under "Total Solids in an Entire Loaf of Bread") comminute the sample by passing it twice through a food chopper.

(b) Raisin bread is baked in units each of which weighs one-half pound or more after cooling. Raisin rolls or raisin buns are baked in units each of which weighs less than one-half pound after cooling.

§ 17.5 *Whole wheat bread, graham bread, entire wheat bread, and whole wheat rolls, graham rolls, entire wheat rolls, or whole wheat buns, graham buns, entire wheat buns; identity; label statement of optional ingredients.* (a) Each of the foods whole wheat bread, graham bread, entire wheat bread, whole wheat rolls, graham rolls, entire wheat rolls, whole wheat buns, graham buns, entire wheat buns conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for bread, rolls, and buns by § 17.1 (a) and (c), except that:

(1) The dough is made with whole wheat flour, and no flour is used therein.

(2) The limitation prescribed by § 17.1 (a) (2) on the quantity and composition of dairy ingredients does not apply.

(3) The total weight of calcium propionate, sodium propionate, or mixtures of these used is not more than 0.38 part for each 100 parts by weight of the whole wheat flour used.

As used in this section, the term "flour," unqualified, includes flour, enriched flour, bromated flour, enriched bromated flour, and phosphated flour; the term "whole wheat flour" includes whole wheat flour and bromated whole wheat flour. The potassium bromate in any bromated whole wheat flour used shall be deemed to be an optional ingredient in the whole wheat bread or whole wheat rolls.

(b) Whole wheat bread, graham bread, or entire wheat bread is baked in units each of which weighs one-half pound or more after cooling. Whole wheat rolls, graham rolls, entire wheat rolls, or whole wheat buns, graham buns, entire wheat buns are baked in units each of which weighs less than one-half pound after cooling.

PART 18—MILK AND CREAM; DEFINITIONS AND STANDARDS OF IDENTITY

Sec.

18.500 Cream class of food; identity.
18.501 Light cream, coffee cream, table cream; identity.
18.510 Whipping cream class of food; identity.
18.511 Light whipping cream; identity.
18.515 Heavy cream, heavy whipping cream; identity.
18.520 Evaporated milk; identity; label statement of optional ingredients.
18.525 Concentrated milk, plain condensed milk; identity; label statement of optional ingredients.
18.530 Sweetened condensed milk; identity.
18.535 Condensed milks which contain corn sirup; identity.
18.540 Dried skim milk, powdered skim milk, skim milk powder; identity.

AUTHORITY: §§ 18.500 to 18.540 issued under sec. 701 (a), 52 Stat. 1055; 21 U. S. C. 371 (a). Interpret or apply sec. 401, 52 Stat. 1046, 68 Stat. 54; 21 U. S. C. 341.

§ 18.500 *Cream class of food; identity.* Cream is the class of food which is the sweet, fatty liquid or semi-liquid separated from milk, with or without the addition thereto and intimate admixture therewith of sweet milk or sweet skim milk. It may be pasteurized and if it contains less than 30 percent of milk fat as determined by the method referred to in this section, it may be homogenized. It contains not less than 18 percent of milk fat, as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agriculture Chemists," Fourth Edition, 1935, page 277 [Ed. note, 8th edition, 1955, p. 261, sec. 15.61] under "Fat, Roese-Gottlieb Method—Official." The word "milk" as used in this section means cow's milk.

§ 18.501 *Light cream, coffee cream, table cream; identity.* Light cream, coffee cream, table cream, conforms to the definition and standard of identity prescribed for the cream class of food by § 18.500, except that it contains less than 30 percent of milk fat, as determined by the method referred to in such section.

§ 18.510 *Whipping cream class of food; identity.* Whipping cream is the class of food which conforms to the definition and standard of identity prescribed for the cream class of food by § 18.500, except that it contains not less than 30 percent of milk fat, as determined by the method referred to in such section.

§ 18.511 *Light whipping cream; identity.* Light whipping cream conforms to the definition and standard of identity prescribed for the whipping cream class of food by § 18.510, except that it contains less than 36 percent of milk fat, as determined by the method referred to in § 18.500.

§ 18.515 *Heavy cream, heavy whipping cream; identity.* Heavy cream, heavy whipping cream, conforms to the definition and standard of identity prescribed for the whipping cream class of food by § 18.510, except that it contains not less than 36 percent of milk fat, as determined by the method referred to in § 18.500.

§ 18.520 *Evaporated milk; identity; label statement of optional ingredients.* (a) Evaporated milk is the liquid food made by evaporating sweet milk to such point that it contains not less than 7.9 percent of milk fat and not less than 25.9 percent of total milk solids. It may contain one or both of the following optional ingredients:

(1) Disodium phosphate or sodium citrate or both, or calcium chloride, added in a total quantity of not more than 0.1 percent by weight of the finished evaporated milk.

(2) Vitamin D in such quantity as to increase the total vitamin D content to not less than 25 U. S. P. units per fluid ounce of the finished evaporated milk. It may be homogenized. It is sealed in a container and so processed by heat as to prevent spoilage.

(b) When the optional ingredient specified in paragraph (a) (2) of this section is present, the label shall bear the statement "with increased vitamin D content" or "vitamin D content increased." Such statement shall immediately and conspicuously precede or follow the name "Evaporated Milk," without intervening written, printed, or graphic matter, wherever such name appears on the label so conspicuously as to be easily seen under customary conditions of purchase.

(c) For the purpose of this section:

(1) The word "milk" means cow's milk.

(2) Such milk may be adjusted, before or after evaporation, by the addition or abstraction of cream or sweet skim milk, or by the addition of concentrated sweet skim milk.

(3) The quantity of milk fat is determined by the method prescribed under "Fat—Official" on page 249 [Ed. note, 8th edition, 1955, p. 263, sec. 15.74] and the quantity of total milk solids is determined by the method prescribed under "Total Solids—Official" on page 248 [Ed. note, 8th edition, 1955, p. 263, sec. 15.72] of "Official Methods of Analysis of the Association of Official Agricultural Chemists," Seventh Edition, 1950.

(4) Vitamin D content may be increased by the application of radiant energy or by the addition of a concentrate of vitamin D (with any accompanying vitamin A when such vitamin D in such concentrate is obtained from natural sources) dissolved in a food oil; but if such oil is not milk fat the quantity thereof added is not more than 0.01 percent of the weight of the finished evaporated milk.

(5) The quantity of vitamin D is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Agricultural Chemists," Seventh Edition, 1950, page 788 et seq., [Ed. note, 8th edition, 1955, p. 839 et seq., secs. 38.64, 38.75], under the heading "Vitamin D in Milk—Official."

§ 18.525 *Concentrated milk, plain condensed milk; identity; label statement of optional ingredients.* Concentrated milk, plain condensed milk, conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for evaporated milk by § 18.520, except that:

(a) It is not processed by heat;

(b) Its container may be unsealed; and

(c) Optional ingredient § 18.520 (a) (1) is not used.

§ 18.530 *Sweetened condensed milk; identity.* (a) Sweetened condensed milk is the liquid or semi-liquid food made by evaporating a mixture of sweet milk and refined sugar (sucrose) or any combination of refined sugar (sucrose) and refined corn sugar (dextrose) to such point that the finished sweetened condensed milk contains not less than 28.0 percent of total milk solids and not less than 8.5 percent of milk fat. The quantity of refined sugar (sucrose) or combination of such sugar and refined corn sugar (dextrose) used is sufficient to prevent spoilage.

(b) For the purpose of this section:

(1) The word "milk" means cow's milk.

(2) Such milk may be adjusted, before or after evaporation, by the addition or abstraction of cream or sweet skim milk, or the addition of concentrated sweet skim milk.

(3) Milk fat is determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fourth Edition, 1935, page 281 [Ed. note, 8th edition, 1955, p. 264, sec. 15.86], under "Fat—Official."

§ 18.535 *Condensed milks which contain corn sirup; identity.* (a) Condensed milks which contain corn sirup are the foods each of which conforms to the definition and standard of identity prescribed for sweetened condensed milk by § 18.530 except that corn sirup or a mixture of corn sirup and sugar is used instead of sugar or a mixture of sugar and dextrose. For the purpose of this section the term "corn sirup" means a clarified and concentrated aqueous solution of the porducts obtained by the incomplete hydrolysis of cornstarch, and includes dried corn sirup; the solids of such corn sirup contain not less than 40 percent by weight of reducing sugars, calculated as anhydrous dextrose.

(b) The name of each such food is:

(1) "Corn sirup condensed milk," "condensed milk with corn sirup," or "condensed milk prepared with corn sirup," if corn sirup alone is used; or

(2) "____% Corn sirup solids ____% sugar condensed milk," "Condensed milk with ____% corn sirup solids ____% sugar," or "Condensed milk prepared with ____% corn sirup solids ____% sugar," if a mixture of corn sirup and sugar is used, the blanks being filled in with the whole numbers nearest the actual percentages of corn sirup solids and sugar in such food; alternately "____% sugar" may precede "____% corn sirup solids" in such names.

§ 18.540 *Dried skim milk, powdered skim milk, skim milk powder; identity.* Dried skim milk, powdered skim milk, skim milk powder, is the food made by drying sweet skim milk. It contains not more than 5 percent of moisture, as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fourth Edition, 1935, page 282 [Ed. note, 8th edition, 1955, p. 265, sec. 15.93], under the caption "Moisture—Tentative." The term "skim milk" as used in this section, means cow's milk from which the milk fat has been separated.

NOTE: 58 Stat. 108, 21 U. S. C. 321c, provides a statutory definition for this food under the names: "Non-fat dry milk solids" and "defatted milk solids."

PART 19—CHEESES; PROCESSED CHEESES; CHEESE FOODS; CHEESE SPREADS, AND RELATED FOODS; DEFINITIONS AND STANDARDS OF IDENTITY

Sec.
19.500 Cheddar cheese, cheese; identity.
19.502 Cheddar cheese for manufacturing; identity.
19.505 Washed curd cheese, soaked curd cheese; identity.
19.507 Washed curd cheese for manufacturing; identity.
19.510 Colby cheese; identity.
19.512 Colby cheese for manufacturing; identity.
19.515 Cream cheese; identity; label statement of optional ingredients.
19.520 Neufchatel cheese; identity; label statement of optional ingredients.
19.525 Cottage cheese; identity.
19.530 Creamed cottage cheese; identity.
19.535 Granular cheese, stirred curd cheese; identity.
19.537 Granular cheese for manufacturing; identity.
19.540 Swiss cheese, emmentaler cheese; identity.
19.542 Swiss cheese for manufacturing; identity.
19.543 Gruyere cheese; identity.

Sec.
19.545 Brick cheese; identity.
19.547 Brick cheese for manufacturing; identity.
19.550 Muenster cheese, munster cheese; identity.
19.555 Edam cheese; identity.
19.560 Gouda cheese; identity.
19.565 Blue cheese; identity.
19.567 Gorgonzola cheese; identity.
19.570 Roquefort cheese, sheep's milk blue-mold cheese, blue-mold cheese from sheep's milk; identity.
19.575 Limburger cheese; identity.
19.580 Monterey cheese; Monterey jack cheese; identity.
19.585 High-moisture jack cheese; identity.
19.590 Provolone cheese, pasta filata cheese; identity.
19.591 Caciocavallo siciliano cheese; identity.
19.595 Parmesan cheese, reggiano cheese; identity.
19.610 Romano cheese; identity.
19.615 Asiago fresh cheese, asiago soft cheese; identity.
19.620 Asiago medium cheese; identity.
19.625 Asiago old cheese; identity.
19.635 Cook cheese, koch kaese; identity.
19.637 Sap sago cheese; identity.
19.639 Gammelost cheese; identity.
19.650 Hard cheeses; identity.
19.655 Semisoft cheeses; identity; label statement of optional ingredients.
19.660 Semisoft part-skim cheeses; identity; label statement of optional ingredients.
19.665 Soft ripened cheeses; identity; label statement of optional ingredients.
19.670 Spiced cheeses; identity; label statement of optional ingredients.
19.675 Part-skim spiced cheeses; identity; label statement of optional ingredients.
19.680 Hard grating cheeses; identity; label statement of optional ingredients.
19.685 Skim-milk cheese for manufacturing; identity.
19.750 Pasteurized process cheese; identity; label statement of optional ingredients.
19.751 Pasteurized blended cheese; identity; label statement of optional ingredients.
19.755 Pasteurized process cheese with fruits, vegetables, or meats; identity; label statement of optional ingredients.
19.760 Pasteurized process pimento cheese; identity.
19.763 Pasteurized blended cheese with fruits, vegetables, or meats; identity; label statement of optional ingredients.
19.765 Pasteurized process cheese food; identity; label statement of optional ingredients.
19.770 Pasteurized process cheese food with fruits, vegetables, or meats; identity; label statement of optional ingredients.
19.775 Pasteurized process cheese spread; identity; label statement of optional ingredients.
19.776 Pasteurized cheese spread; identity; label statement of optional ingredients.
19.780 Pasteurized process cheese spread with fruits, vegetables, or meats; identity; label statement of optional ingredients.
19.781 Pasteurized cheese spread with fruits, vegetables, or meats; identity; label statement of optional ingredients.
19.782 Cream cheese with other foods; identity; label statement of optional ingredients.
19.783 Pasteurized neufchatel cheese spread with other foods; identity; label statement of optional ingredients.

Sec.
19.785 Cold-pack cheese, club cheese, comminuted cheese; identity; label statement of optional ingredients.
19.787 Cold-pack cheese food; identity; label statement of optional ingredients.
19.788 Cold-pack cheese food with fruits, vegetables, or meats; identity; label statement of optional ingredients.

AUTHORITY: §§ 19.500 to 19.788 issued under sec. 701, 52 Stat. 1055; 21 U. S. C. 371. Interpret or apply sec. 401, 52 Stat. 1046, 68 Stat. 54; 21 U. S. C. 341.

§ 19.500 *Cheddar cheese, cheese; identity.* (a) Cheddar cheese, cheese, is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 39 percent of moisture, and its solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in paragraph (c) of this section. If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35° F. for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is so cut, stirred, and heated with continued stirring, as to promote and regulate the separation of whey and curd. The whey is drained off, and the curd is matted into a cohesive mass. The mass is cut into slabs, which are so piled and handled as to promote the drainage of whey and the development of acidity. The slabs are then cut into pieces, which may be rinsed by sprinkling or pouring water over them, with free and continuous drainage; but the duration of such rinsing is so limited that only the whey on the surface of such pieces is removed. The curd is salted, stirred, further drained, and pressed into forms. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of cheddar cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) Determine moisture by the method prescribed on page 262 (15.124) [Ed. note, 8th edition, 1955, p. 278, sec. 15.129], under "Moisture—Official," and milk fat by the method prescribed on page 263 (15.131) [Ed. note, 8th edition, 1955, p. 279, sec. 15.136], under "Fat—Official," of "Official Methods of Analysis of the Association of Official Agricultural Chemists," Seventh Edition, 1950. Subtract the percent of moisture found from 100; divide the remainder into the percent milk fat found. The quotient, multiplied by 100, shall be considered to be the percent of milk fat contained in the solids.

(d) For the purposes of this section:

(1) The word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk solids used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F. for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. Cheddar cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 3 micrograms when tested by the method prescribed in paragraph (e) of this section.

(e) The method referred to in paragraph (d) (2) of this section is as follows:

I. *Reagents*—1. *Buffers*—a. *Barium borate-hydroxide buffer.* Dissolve 25.0 gm. of c. p. barium hydroxide ($Ba(OH)_2 \cdot 8H_2O$, fresh, not deteriorated) in distilled water and dilute to 500 ml. Dissolve, in another flask or cylinder, 11.0 gm. of c. p., boric acid (H_3BO_3) and dilute to 500 ml. Warm each to 50° C. (122° F.), mix the two together, stir, cool to approximately 20° C. (68° F.), filter, and stopper the filtrate tightly (pH approximately 10.6). The buffer prepared thus is designated as the 25–11 buffer, the figures indicating the grams per liter of each of the respective reagents.

b. *Color-development buffer.* Dissolve 6.0 gm. of sodium metaborate ($NaBO_2$) and 20 gm. of sodium chloride in water and dilute to a liter with water (pH 9.8).

c. *Color-dilution buffer.* Dilute 100 ml. of color-development buffer 1–b to a liter with water.

d. *Standard borax buffer, 0.01-molar, for checking pH meter, pH 9.18 at 25° C.*[1] Dissolve 0.9544 gm. of pure borax (Bureau of Standards Sample 187) in distilled water (distilled recently or freshly boiled and cooled) and dilute to 250 ml. Keep stoppered tightly.

2. *Buffer substrates.* Specify phenol-free crystalline disodium phenyl phosphate.

a. *For evaluating pasteurization.* Dissolve 0.10 gm. of the phenyl phosphate in 100 ml. of the appropriate (table 1) barium borate-hydroxide buffer 1–a.

b. *For quantitative results with raw-milk cheese.* Dissolve 0.20 gm. of the phenyl phosphate in 100 ml. of the appropriate (table 1) barium borate-hydroxide buffer 1–a.

3. *Protein precipitants*—a. *Zinc-copper precipitant for unripened cheese.* Dissolve 6.0 gm. of zinc sulfate ($ZnSO_4 \cdot 7H_2O$) and 0.1 gm. of copper sulfate ($CuSO_4 \cdot 5H_2O$) in water and dilute to 100 ml. with water. The precipitant prepared thus is designated as the 6.0–0.1 precipitant.

b. *Zinc precipitant for ripened cheese.* Dissolve 6.0 gm. of zinc sulfate in water and dilute to 100 ml. with water. This precipitant is designated as the 6.0 precipitant.

4. *BQC* (*2,6-dibromoquinone-chloroimine solution*) (*Gibbs' reagent*): Dissolve 40 mg. of BQC powder in 10 ml. of absolute methyl alcohol and transfer to a dark-colored dropper bottle. This reagent remains stable for at least a month if kept in the ice tray of a refrigerator. Do not use it after it begins to turn brown.

5. *Other reagents*—a. *Copper sulfate, 0.05 percent, for standards.* Dissolve 0.05 gm. of copper sulfate in water and dilute to 100 ml.

b. *Butyl alcohol.* Specify *n*-butyl alcohol, boiling point 116°–118° C. To adjust the pH, mix 50 ml. of the color-development buffer 1–b with a liter of the butyl alcohol.

6. *Phenol standards*—a. *Stock solution.* Weigh accurately 1.0 gm. of pure phenol, transfer to a liter volumetric flask, dilute to a liter with water, and mix. One ml. contains 1 mg. (0.001 gm.) of phenol. Use this stock solution to prepare standard solutions. It is stable for several months in the refrigerator.

b. *Preparation of standards.* Dilute 10.0 ml. of the stock solution 6–a to a liter with water, and mix. One ml. contains 10 micrograms (0.00001 gm., 10 gammas, or 10 units) of phenol. Use this standard solution to prepare more dilute standard solutions; e. g., dilute 5, 10, 30, and 50 ml. to 100 ml. with water to prepare standard solutions containing 0.5, 1.0, 3.0, and 5.0 gammas or units of phenol per milliliter, respectively. Keep standard solutions in the refrigerator.

In a similar manner, prepare from the stock solution such more concentrated standard solutions as may be needed, containing, for example, 20, 30, and 40 units per milliliter.

Measure appropriate quantities of the phenol standard solution into a series of tubes (preferably graduated at 5.0 and 10.0 ml.) to provide a suitable range of standards as needed, containing 0 (control blank), 0.5, 1.0, 3.0, 5.0, 10.0, etc., to 30 or 40 units. To increase the brightness of the blue color and improve the stability of the standards, add 1.0 ml. of 0.05 percent copper sulfate solution 5–a to each.

Add 5.0 ml. of color dilution buffer 1–c and add water to bring the volume to 10.0 ml. Add 4 drops (0.08 ml.) of BQC 4, mix, and allow to develop for 30 minutes at room temperature. If the butyl alcohol extraction method is to be used in the test, extract the standards as described under III Conducting the Test.

Read the color intensities with a photometer, subtract the value of the blank from the value of each phenol standard, and prepare a standard curve (straight line). When the standards are to be used for visual comparisons they should be stored in a refrigerator.

II. *Sampling*—1. *Hard cheese.* Take a sample from the interior with a *clean* Roquefort trier, place in a small tube, stopper the tube, and keep it in a refrigerator.

2. *Soft and semisoft ripened cheese.* Harden the cheese by chilling it in the freezing chamber of a refrigerator. Taking special precaution to avoid contaminating the sample with phosphatase that may be present on the surface, use either of the following methods for sampling:

a. Cut a portion from the end of the loaf or from the side of the cheese, extending in at least 2 inches if possible or to a point somewhat beyond the center in the case of a small cheese. Cut a slit ¼ to ½ inch deep at least halfway around the portion and midway between the top and bottom. Break the portion into two parts, pulling it apart so that it breaks on a line with the slit, being careful not to contaminate the freshly exposed, broken surface. Remove the sample from the freshly exposed surface at or near the center of the cheese.

b. Remove the surface of the area to be sampled—e. g., the end and the adjacent sides—with a clean knife or spatula, to a depth of ¼ inch. Clean the instrument and hands with hot water and phenol-free soap and wipe them dry. Remove the freshly exposed surface to a similar or greater depth and repeat the cleaning. Then take the sample from the center of the freshly exposed area, preferably at or near the center of the cheese in the case of a small cheese.

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[1] All pH values reported herein were determined at 25° C. or corrected to that temperature.

3. *Process cheese, spreads, etc.* Take the sample from beneath the surface with a clean knife or spatula.

Avoid the use of samples contaminated with mold.

4. *Preservation.* If a preservative is necessary, put 1 to 3 ml. of chloroform in the container, cover with a plug of cotton, insert sample and stopper container tightly. Label preserved samples, "*Poison*—Preservative added."

III. *Conducting the test.* 1. Weigh, on a clean balance pan or watch glass, a 0.50-gm. sample (preferably two samples in duplicate) and place in a culture tube 16 or 18 x 150 mm. Similarly, weigh another sample and place in a tube as a control or blank. If the cheese is sticky, weigh the sample on a piece of wax paper about 1 x 1 inch and insert the paper with the sample into the tube. Macerate the blank and the test with a glass rod about 8 x 180 mm.

2. Add to the blank 1.0 ml. of the appropriate (Table 1) barium buffer 1-a (without substrate added), macerate with the rod, leave the rod in the tube, heat for about a minute to at least 85° C. (185° F.) in a beaker of boiling water with the beaker covered so that the entire tube becomes heated to approximately 85° C., cool to room temperature, and macerate again with the rod.

3. Add to the test 1.0 ml. of the appropriate (Table 1) barium buffer substrate 2-a or 2-b, and macerate.

From this point, treat the blank and the test in a similar manner.

Add 9.0 ml. of the appropriate barium buffer substrate 2-a or 2-b (total, 10.0 ml. added), and mix. The rod may be left in the tube during incubation; or, if removing it at this point, cut a piece of filter paper approximately 1 x 1 inch, wrap and hold it tightly around the rod, rotate the rod while withdrawing it from within the tube so as to wipe the rod clean, insert the paper with the adhering fat into the tube, and stopper the tube.

4. Incubate in a water bath at 37°–38° C. (99°–100° F.) for 1 hour, mixing or shaking the contents occasionally.

5. Place in a beaker of boiling water for nearly a minute, heating to 85° C. (185° F.), and cool to room temperature.

6. Pipet in 1.0 ml. of the zinc precipitant 3-b for ripened cheese or the zinc-copper precipitant 3-a for unripened cheese, and mix thoroughly (pH of mixture, 9.0–9.1).

7. Filter (5-cm. funnel, 9-cm. Whatman No. 42 or No. 2 paper recommended), and collect 5.0 ml. of filtrate in a tube, preferably graduated at 5.0 and 10.0 ml.

8. Add 5.0 ml. of color-development buffer 1-b (pH of mixture, 9.3–9.4).

9. Add four drops [1] of BQC 4, mix, and allow the color to develop for 30 minutes at room temperature.

10. Determine the amount of blue color by either of two methods:

a. *With a photometer.* Read the color intensity of the blank and that of the test, subtract the reading of the blank from that of the test, and convert the result into phenol equivalents by reference to the standard curve described under "Phenol standards." The butyl alcohol extraction method is ordinarily unnecessary when using a photometer.

b. *With visual standards.* For quantitative results in borderline instances, e. g., tests yielding 0.5 to 5 units of color, extract with butyl alcohol 5-b. Add 5.0 ml. of the alcohol and invert the tube slowly several times Centrifuge if necessary to increase the clearness of the alcohol layer. Compare the blue color with the colors of standards in the alcohol.

With samples yielding more than 5 units, compare the colors in aqueous tests with those of aqueous standards.

11. *Dilution method for quantitative results.* In tests that are observed during color development to be strongly positive, e. g., 20 units or more, in which four drops of BQC may be much less than sufficient to combine with all of the phenol, pipet an appropriate proportion of the contents into another tube, make up to 10.0 ml. with color-dilution buffer 1-c, and add two drops more of BQC in the case of unripened cheese or four drops in the case of ripened cheese. With each test, dilute and treat the blank in the corresponding manner. Dilute each strongly positive test thus until the final color is within the range of the standards or photometer. Allow 30 minutes for color development after the last addition of BQC, and make the reading at the end of the 30-minute period. Multiply, for example, by 2 for a 5+5 dilution, 10 for a 1+9 dilution, and 50 for a 1+9 followed by a 2+8 dilution.

Alternatively, to reduce the amount of yellow off color, add two instead of four drops of BQC after each dilution, and allow the color to develop. Then test the completeness of color development by adding a third drop; repeat the dilution procedure until the addition of an extra drop does not cause any further increase in the amount of blue color.

12. *Calculation and evaluation of results.* When using 0.5 gm. of sample and adding a total of 11.0 ml. of liquid, multiply the value of the reading by 1.1 to convert it to units of color or phenol equivalents per 0.25 gm. of cheese. The result may, if desired, be converted to phenol equivalents per 1 gm. by multiplying by 4.4

IV. *Photometric determination.* To read the color in aqueous solution, use a filter with maximum light transmission in the region of 610 m_μ wave length.

To read the color in butyl alcohol, extract the color as described above. If necessary, centrifuge the sample for 5 minutes to break the emulsion and to remove the moisture suspended in the alcohol layer. A Babcock centrifuge can be adapted for this purpose by making special tube holders as follows: Slice a section ¼ inch thick from a rubber stopper of suitable diameter to fit in the bottom of the centrifuge cup. Glue together two cork stoppers of appropriate diameter, bore through the center a hole of proper size to hold the tube snugly, and insert the double-cork section into the cup. After centrifuging, remove nearly all of the butyl alcohol by means of a pipet with a rubber bulb on the top end. Filter the alcohol into the photometer cell and read with a filter with maximum light transmission in the region of 650 m_μ wave length.

If more than approximately 4 ml. of butyl alcohol is required for the photometer used, conduct the test in a larger tube and extract the color, in both the test and the standards, with the necessary quantity of butyl alcohol rather than with 5 ml. specified above.

V. *Precautions.* The length of time that the crystalline disodium phenyl phosphate and the BQC powder will remain stable can be increased greatly by keeping them in the freezing chamber of a refrigerator, and by keeping them dry.

The glassware, stoppers, and sampling tools should be scrupulously clean, and it is desirable to soak them in hot, running water after cleaning.

The solid barium hydroxide and the barium buffer must be kept stoppered tightly to prevent absorption of carbon dioxide. Phenolic contamination from plastic closures on reagent bottles has been encountered, and therefore the use of plastic closures should be avoided. Rubber stoppers should not be used in flasks in which butyl alcohol is stored. Glass or cork stoppers should be used.

VI. *Modifications for different cheeses.* Different kinds of cheese and cheeses of different ages have different buffering capacities, and therefore some of them require modification of concentrations of the reagents. The modifications of the barium buffer needed to produce optimal pH conditions during incubation (9.85–10.20), and of the precipitant to yield uniformly clear filtrates and to minimize interference during color development under optimal pH conditions (9.3–9.4), are specified in Table I.

With some samples, especially those of unknown history, slight deviations from the optimal pH range may occur, but such deviations do not very materially affect the results. For example, pH values as low as 9.6 or as high as 10.35 during incubation have been found to result in an average decrease of not more than 20 percent below the maximum in the quantity of phenol liberated. The use of the 25–11 buffer substrate with samples for which the 27–11 buffer substrate is specified yields pH values not lower than 9.8.

In testing cheese of unknown history or age, information as to the percentage of solids, especially the nonfat solids, is useful as an indication of the correct buffer to use; cheese with a relatively high percentage of nonfat solids generally requires the use of a relatively concentrated buffer to adjust the pH of the mixture correctly.

For precise quantitative results on unknown samples, adjust the pH to 10.0–10.05 for the incubation.

Cottage cheese curd is heated in the presence of considerable acid during manufacture, and therefore its phosphatase values are comparatively low. Alternatively, to increase the sensitivity of the test on cottage cheese, apply the following modifications: Use a 1.0-gm. sample, 27–11 buffer substrate, 2-hour incubation, and 6.0–0.1 precipitant.

Table I—PHOSPHATASE TEST MODIFICATIONS FOR DIFFERENT KINDS OF CHEESE AND CHEESE OF DIFFERENT AGES

Kind of cheese	Age or extent of curing; other details	Buffer for optimal pH (9.85–10.20)	Precipitant
Cheddar, granular, stirred curd, hard cheese	1 week	[1] 25–11	[2] 6.0–0.0
	1 week–1½ months	25–11	[3] 6.0
	1½–4 months	26–11	6.1
	4 months	27–11	6.0
Washed curd, soaked curd, colby	1 week	25–11	6.0–0.0
	1 week–2 months	25–11	6.0
	2 months	26–11	6.1
Swiss, gruyere	1 week	25–11	6.0–0.1
	1 week–1 month	25–11	6.0
	1–3 months	26–11	6.0
	3 months	27–11	6.0
Brick, muenster	1 week	25–11	6.0–0.1
	1 week–1 month	25–11	6.0
	1–2 months	25–11	6.0
	2 months	26–11	6.0

[1] Grams $Ba(OH)_2.8H_2O$ and H_3BO_3 per liter, respectively.
[2] Grams $ZnSO_4.7H_2O$ and $CuSO_4.5H_2O$ per 100 ml., respectively.
[3] Grams $ZnSO_4.7H_2O$ per 100 ml.

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[1] For merely detecting underpasteurization, in testing unripened cheese, two drops is sufficient, provided the visual standards are prepared likewise with two drops.

Table I—Phosphatase Test Modifications for Different Kinds of Cheese and Cheese of Different Ages—Continued

Kind of cheese	Age or extent of curing; other details	Buffer of optimal pH (9.85-10.20)	Precipitant
Edam, gouda	1 week	25-11	6.0-0.1
	1 week-2 months	25-11	6.0-0.1
	2-4 months	26-11	6.0
	4 months	27-11	6.0
Blue mold, blue	1 week	25-11	6.0-0.1
	1 week-1 month	26-11	6.0
	1-4½ months	27-11	6.0
	4½ months	28-11	6.0
Camembert, limburger	1 week	25-11	6.0-0.1
	1 week-1 month	25-11	6.0
	1-2 months	26-11	6.0
	2 months	27-11	6.0
Monterey	1 week	25-11	6.0-0.1
	1 week-2 months	25-11	6.0
	2 months	26-11	6.0
High-moisture jack	1 week	25-11	6.0-0.1
	1 week-2½ months	25-11	6.0
	2½ months	26-11	6.0
Provolone, pasta filata	1 week	25-11	6.0-0.1
	1 week-1 month	25-11	6.0
	1-3 months	26-11	6.0
	3 months	27-11	6.0
Parmesan, reggiano, monte, modena, romano, asiago old.	1 week	25-11	6.0-0.1
	1 week-2 months	26-11	6.0
	2-6 months	27-11	6.0
	6 months-1 year	28-11	6.0
	1 year	29-11	6.0
Asiago fresh	Same as chedder		
Asiago medium	1 week	25-11	6.0-0.1
	1 week-1 month	25-11	6.0
	1-3 months	26-11	6.0
	3 months	27-11	6.0
Gorgonzola	Same as blue		
Cottage, cook cheese, koch kaese	Dry	25-11	6.0-0.1
	Moist	[4] 25-11 (8+2)	4.5-0.1
Cream cheese		25-11 (7+3)	6.0-0.1
Semisoft cheese	1 week	25-11	6.0-0.1
	1 week-1 month	25-11	6.0
	1 month	26-11	6.0
Soft ripened cheese	1 week	25-11	6.0-0.1
	1 week-1 month	25-11	6.0
	1 month	26-11	6.0
Nokkelost, kuminost, sage cheese	1 week	25-11	6.0-0.1
	1 week-1½ months	25-11	6.0
	1½-4 months	26-11	6.0
	4 months	27-11	6.0
Pasteurized process, pasteurized process pimento, pasteurized process with fruits, meats, etc.	Soft, mild	25-11	6.0
	Medium, firm	26-11	6.0
	Firm, sharp (including swiss, gruyere)	27-11	6.0
Pasteurized process cheese foods; pasteurized process cheese foods with fruits, meats, etc.	Same as pasteurized process		
Pasteurized process cheese spreads; pasteurized process cheese spreads with fruits, meats, etc.	Soft, high moisture, including cream spreads.	25-11	6.0
	Less soft, including blue	26-11	6.0
Cold-pack, club; cold-pack cheese foods; cold-pack cheese foods with fruits, meats, etc.	Mild to medium flavored, soft	26-11	6.0
	Sharp, firm	27-11	6.0

[4] 8 parts of 25-11 buffer plus 2 parts of water.

§ 19.502 *Cheddar cheese for manufacturing; identity.* Cheddar cheese for manufacturing conforms to the definition and standard of identity prescribed for cheddar cheese by § 19.500, except that the milk is not pasteurized, and curing is not required.

§ 19.505 *Washed curd cheese, soaked curd cheese; identity.* (a) Washed curd cheese, soaked curd cheese, is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 42 percent of moisture, and its solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in § 19.500 (c). If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35° F. for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is so cut, stirred, and heated with continued stirring, as to promote and regulate the separation of whey and curd. The whey is drained off, and the curd is matted into a cohesive mass. The mass is cut into slabs, which are so piled and handled as to promote the drainage of whey and the development of acidity. The slabs are then cut into pieces, cooled in water, and soaked therein until the whey is partly extracted and water is absorbed. The curd is drained, salted, stirred, and pressed into forms. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of washed curd cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk solids used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F. for a period of not less than 30 minutes or for a time and at a temperature equivalent thereto in phosphatase destruction. Washed curd cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 3 micrograms when tested by the method prescribed in § 19.500 (e).

§ 19.507 *Washed curd cheese for manufacturing; identity.* Washed curd cheese for manufacturing conforms to the definition and standard of identity prescribed for washed curd cheese by § 19.505, except that the milk is not pasteurized, and curing is not required.

§ 19.510 *Colby cheese; identity.* (a) Colby cheese is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 40 percent of moisture, and its solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in § 19.500 (c). If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35° F. for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is so cut, stirred, and heated with continued stirring, as to promote and regulate the separation of whey and curd. A part of the whey is drained off, and the curd is cooled by adding water, the stirring being continued so as to prevent the pieces of curd from matting. The curd is drained, salted, stirred, further drained, and pressed into forms. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of colby cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids, water, in a quantity sufficient to reconstitute

any concentrated skim milk or nonfat dry milk solids used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F. for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. Colby cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 3 micrograms when tested by the method prescribed in § 19.500 (e).

§ 19.512 *Colby cheese for manufacturing; identity.* Colby cheese for manufacturing conforms to the definition and standard of identity prescribed for colby cheese by § 19.510, except that the milk is not pasteurized, and curing is not required.

§ 19.515 *Cream cheese; identity; label statement of optional ingredients.* (a) Cream cheese is the soft uncured cheese prepared by the procedure set forth in paragraph (b) of this section. The finished cream cheese contains not less than 33 percent of milk fat and not more than 55 percent of moisture, as determined, respectively by the methods prescribed under "Fat—Official" on page 302 and under "Moisture—Official" on page 301 of "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fifth Edition, 1940. (These methods appear in the Eighth Edition, 1955, at pages 279 and 278.)

(b) (1) Cream or a mixture of cream with one or more of the dairy ingredients specified in subparagraph (3) of this paragraph is pasteurized and may be homogenized. To such cream or mixture harmless lactic-acid-producing bacteria, with or without rennet, are added, and it is held until it becomes coagulated. The coagulated mass may be warmed; it may be stirred; it is then drained. The curd may be pressed, chilled, worked, seasoned with salt; it may be heated, with or without added cream or one or more of the dairy ingredients specified in subparagraph (3) of this paragraph or both, until it becomes fluid, and it may then be homogenized or otherwise mixed.

(2) In the preparation of cream cheese one or any mixture of two or more of the optional ingredients gum karaya, gum tragacanth, carob bean gum, gelatin, or algin may be used; but the quantity of any such ingredient or mixture is such that the total weight of the solids contained therein is not more than 0.5 percent of the weight of the finished cream cheese.

(3) The dairy ingredients referred to in subparagraph (1) of this paragraph are milk, skim milk, concentrated milk, concentrated skim milk, and nonfat dry milk solids. If concentrated milk, concentrated skim milk, or nonfat dry milk solids is used, water may be added in a quantity not in excess of that removed when the milk or skim milk was concentrated or dried.

(4) For the purposes of this section, the term "milk" means sweet milk of cows, "skim milk" means milk from which the milk fat has been separated, and "concentrated skim milk" means skim milk from which a portion of the water has been removed by evaporation.

(c) When an optional ingredient listed in paragraph (b) (2) of this section is present in cream cheese, the label shall bear the statement "---------- Added" or "With Added ----------------," the blank being filled in with the word or words "Vegetable Gum" or "Gelatin" or "Algin" or any combination of two or all of these, as the case may be. Wherever the name "Cream Cheese" appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement specified in this section, showing the optional ingredients present shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 19.520 *Neufchatel cheese; identity; label statement of optional ingredients.* (a) Neufchatel cheese is the soft uncured cheese prepared by the procedure set forth in paragraph (b) of this section. The finished neufchatel cheese contains not less than 20 percent but less than 33 percent of milk fat and not more than 65 percent of moisture, as determined, respectively, by the methods prescribed under "Fat—Official" on page 302 and under "Moisture—Official" on page 301 of "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fifth Edition, 1940. (These methods appear in the Eighth Edition, 1955, at pages 279 and 278.)

(b) (1) Milk or a mixture of cream with one or more of the dairy ingredients specified in subparagraph (3) of this paragraph or a mixture of concentrated milk with milk or with water not in excess of that removed when the milk was concentrated is pasteurized and may be homogenized. To such milk or mixture harmless lactic-acid-producing bacteria, with or without rennet, are added and it is held until it becomes coagulated. The coagulated mass may be warmed; it may be stirred; it is then drained. The curd may be pressed, chilled, worked, seasoned with salt; it may be heated, with or without added cream or one or more of the dairy ingredients specified in subparagraph (3) of this paragraph or both, until it becomes fluid, and it may then be homogenized or otherwise mixed.

(2) In the preparation of neufchatel cheese one or any mixture of two or more of the optional ingredients gum karaya, gum tragacanth, carob bean gum, gelatin, or algin may be used; but the quantity of any such ingredient or mixture is such that the total weight of the solids contained therein is not more than 0.5 percent of the weight of the finished neufchatel cheese.

(3) The dairy ingredients referred to in subparagrph (1) of this paragraph are milk, skim milk, concentrated milk, concentrated skim milk, and nonfat dry milk solids. If concentrated milk, concentrated skim milk, or nonfat dry milk solids is used, water may be added in a quantity not in excess of that removed when the milk or skim milk was concentrated or dried.

(4) For the purposes of this section the term "milk" means sweet milk of cows; "skim milk" means milk from which the milk fat has been separated, and "concentrated skim milk" means skim milk from which a portion of the water has been removed by evaporation.

(c) When an optional ingredient listed in paragraph (b) (2) of this section is present in neufchatel cheese, the label shall bear the statement "------------ Added" or "With Added ------------," the blank being filled in with the word or words "Vegetable Gum" or "Gelatin" or "Algin" or any combination of two or all of these, as the case may be. Wherever the name "Neufchatel Cheese" appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement specified in this section, showing the optional ingredients present shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 19.525 *Cottage cheese; identity.* (a) Cottage cheese is the soft uncured cheese prepared by the procedure set forth in paragraph (b) of this section. The finished cottage cheese contains not more than 80 percent of moisture, as determined by the method prescribed under "Moisture—Official" on page 301 of "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fifth Edition, 1940. (This method appears in the Eighth Edition, 1955, at page 278.)

(b) (1) One or more of the dairy ingredients specified in subparagraph (2) of this paragraph is pasteurized; calcium chloride may be added in a quantity of not more than 0.02 percent (calculated as anhydrous calcium chloride) of the weight of the mix; harmless lactic-acid-producing bacteria, with or without rennet, are added and it is held until it becomes coagulated. The coagulated mass may be cut; it may be warmed; it may be stirred; it is then drained. The curd may be washed with water and further drained; it may be pressed, chilled, worked, seasoned with salt.

(2) The dairy ingredients referred to in subparagraph (1) of this paragraph are sweet skim milk, concentrated skim milk, and nonfat dry milk solids. If concentrated skim milk or nonfat dry milk solids is used, water may be added in a quantity not in excess of that removed when the skim milk was concentrated or dried.

(3) For the purposes of this section the term "skim milk" means the milk of cows from which the milk fat has been separated, and "concentrated skim milk" means skim milk from which a portion of the water has been removed by evaporation.

§ 19.530 *Creamed cottage cheese; identity.* (a) Creamed cottage cheese is the soft uncured cheese prepared by mixing cottage cheese with pasteurized cream or a pasteurized mixture of cream with milk or skim milk or both. Such cream or mixture is used in such quantity that the milk fat added thereby is not less than 4 percent by weight of the finished creamed cottage cheese. The finished creamed cottage cheese contains not more than 80 percent of moisture as determined by the method prescribed under "Moisture—Official" on page 301 [Ed. note, 8th edition, 1955, p. 278] of "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fifth Edition, 1940.

(b) For the purposes of this section "milk" means sweet milk of cows and "skim milk" means milk from which the milk fat has been separated.

§ 19.535 *Granular cheese, stirred curd cheese; identity.* (a) Granular cheese, stirred curd cheese, is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 39 percent of moisture, and its solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in § 19.500 (c). If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35° F. for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is so cut, stirred, and heated with continued stirring, as to promote and regulate the separation of whey and curd. A part of the whey is drained off. The curd is then alternately stirred and drained to prevent matting and to remove whey from curd. The curd is then salted, stirred, drained, and pressed into forms. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of granular cheese, may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk solids used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F. for a period of not less than 30 minutes or for a time and at a temperature equivalent thereto in phosphatase destruction. Granular cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 3 micrograms when tested by the method prescribed in § 19.500 (e).

§ 19.537 *Granular cheese for manufacturing; identity.* Granular cheese for manufacturing conforms to the definition and standard of identity prescribed for granular cheese by § 19.535, except that the milk is not pasteurized, and curing is not required.

§ 19.540 *Swiss cheese, emmentaler cheese; identity.* (a) Swiss cheese, emmentaler cheese, is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It has holes, or eyes, developed throughout the cheese. It contains not more than 41 percent of moisture, and its solids contain not less than 43 percent of milk fat, as determined by the methods prescribed in § 19.500 (c). It is not less than 60 days old.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto; harmless propionic-acid-producing bacteria may also be added. Sufficient rennet (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is cut into particles similar in size to wheat kernels. For about 30 minutes the particles are alternately stirred and allowed to settle. The temperature is raised to about 126° F. Stirring is continued until the curd becomes firm. The acidity of the whey at this point, calculated as lactic acid, does not exceed 0.13 percent. The curd is transferred to hoops or forms and pressed until the desired shape and firmness are obtained. The cheese is then salted by immersing it in a saturated salt solution for about 3 days. It is then held at a temperature of about 50° F. to 60° F. for a period of 5 to 10 days, after which it is held at a temperature of about 75° F. until it is approximately 30 days old, or until the so-called eyes form. Salt, or a solution of salt in water, is added to the surface of the cheese at some time during the curing process. The cheese is then stored at a lower temperature for further curing. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of swiss cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section, the word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto cream or skim milk.

§ 19.542 *Swiss cheese for manufacturing; identity.* Swiss cheese for manufacturing conforms to the definition and standard of identity prescribed for swiss cheese by § 19.540, except that the holes, or eyes, have not developed throughout the entire cheese.

§ 19.543 *Gruyere cheese; identity.* (a) Gruyere cheese is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 39 percent of moisture and its solids contain not less than 45 percent of milk fat, as determined by the methods prescribed in § 19.500 (c). It contains small holes, or eyes. It has a mild flavor, due in part to the growth of surface-curing agents. It is not less than 90 days old.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto; harmless propionic-acid-producing bacteria may also be added. Sufficient rennet (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is cut into particles similar in size to wheat kernels. For about 30 minutes the particles are alternately stirred and allowed to settle. The temperature is raised to about 126° F. Stirring is continued until the curd becomes firm. The curd is transferred to hoops or forms, and pressed until the desired shape and firmness are obtained. The cheese is surface-salted while held at a temperature of 48° F. to 54° F. for a few days. It is soaked for 1 day in a saturated salt solution. It is then held for 3 weeks in a salting cellar and wiped every 2 days with brine cloth to insure growth of biological curing agents on the rind. It is then removed to a heating room and held at progressively higher temperatures, finally reaching 65° F., with a relative humidity of 85 to 90 percent, for several weeks, during which time small holes, or so-called eyes, form. The cheese is then stored at a lower temperature for further curing. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of gruyere cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section, the word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto cream or skim milk.

§ 19.545 *Brick cheese; identity.* (a) Brick cheese is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 44 percent of moisture, and its solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in § 19.500 (c). If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35° F. for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, is brought to a temperature of about 88° F. and subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is cut into cubes with sides approximately ⅜-inch long, and stirred and heated so that the temperature rises slowly to about 96° F. The stirring is continued until the curd is sufficiently firm. Part of the whey is then removed, and the mixture diluted with water or salt brine to control the acidity. The curd is transferred to forms, and drained. During drainage it is pressed and turned. After drainage the curd is salted, and the biological curing agents characteristic of brick cheese are applied to the surface. The cheese is then cured to develop the characteristics of brick cheese. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of brick cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk solids used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F. for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. Brick cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 5 micrograms when tested by the method prescribed in § 19.500 (e).

§ 19.547 *Brick cheese for manufacturing; identity.* Brick cheese for manufacturing conforms to the definition and standard of identity prescribed for brick cheese by § 19.545, except that the milk is not pasteurized, and curing is not required.

§ 19.550 *Muenster cheese, munster cheese; identity.* (a) Muenster cheese, munster cheese, is the food prepared from pasteurized milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 46 percent of moisture, and its solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in § 19.500 (c).

(b) Milk, which is pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. After coagulation the mass is divided into small portions, stirred, and heated, with or without dilution with water or salt brine, so as to promote and regulate the separation of whey and curd. The curd is transferred to forms permitting drainage of the whey. During drainage the curd may be pressed and turned. After drainage the curd is removed from the forms and is salted. The surface of the cheese may be rubbed with vegetable oil. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of muenster cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk solids used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F. for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. Muenster cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 3 micrograms when tested by the method prescribed in § 19.500 (e).

§ 19.555 *Edam cheese; identity.* (a) Edam cheese is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 45 percent of moisture, and its solids contain not less than 40 percent of milk fat, as determined by the methods prescribed in § 19.500 (c). If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35° F. for not less than 60 days. Edam cheese is made in ball or loaf shapes, and the surface is covered with a red-colored paraffin or other tightly adhering coating, colored red.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. After coagulation the mass is cut into small cube-shaped pieces with sides approximately ⅜-inch long. The mass is stirred and heated to about 90° F., and so handled by further stirring, heating, dilution with water or salt brine, and salting as to promote and regulate the separation of curd and whey. When the desired curd is obtained, it is transferred to forms permitting drainage of whey. During drainage the curd is pressed and turned. After drainage the curd is removed from the forms and is salted and cured. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of edam cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk solids used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F. for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. Edam cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 3 micrograms when tested by the method prescribed in § 19.500 (e).

§ 19.560 *Gouda cheese; identity.* Gouda cheese conforms to the definition and standard of identity prescribed for edam cheese by § 19.555, except that the fat content of its solids is not less than 46 percent. It is made in the shape of a compressed sphere, in which the compressed sides are parallel and flat. The surface may or may not be covered with red-colored paraffin or similar tightly adhering coating.

§ 19.565 *Blue cheese; identity.* (a) Blue cheese is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It is characterized by the presence of bluish-green mold throughout the cheese. It contains not more than 46 percent moisture, and its solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in § 19.500 (c). It is not less than 60 days old.

(b) Milk, which may be pasteurized or clarified or both, which may be warmed, and which may be homogenized, is subjected to the action of harmless lactic-acid producing bacteria, present in such milk or added thereto. Harmless artificial green or blue coloring in a quantity which neutralizes any natural yellow coloring in the curd may be added. Sufficient rennet (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is cut into smaller portions and allowed to stand for a time. The mixed curd and whey is placed in forms permitting further drainage. While being placed in forms, spores of the mold Penicillium roquefortii are added. The forms are turned several times during drainage. When sufficiently drained, the shaped curd is removed from the forms and salted with dry salt or brine. Perforations are then made in the shaped curd, and it is held at a temperature of approximately 50° F., at 90 to 95 percent relative humidity, until the characteristic mold growth has developed. During storage the surface of the cheese may be scraped to remove surface growth of undesirable microorganisms. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of blue cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk.

(2) Such milk may be bleached by the use of benzoyl peroxide or a mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate; but the weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the milk being bleached, and the weight of the potassium alum, calcium sulfate, and magnesium carbonate, singly or combined, is not more than six times the weight of the benzoyl peroxide used. If milk is bleached in this manner, vitamin A is added to the curd in such quantity as to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(3) Such milk may be adjusted by separating part of the fat therefrom or by adding one or more of the following: Cream, cream which has been treated in the manner provided in subparagraph (2) of this paragraph, concentrated skim milk, nonfat dry milk solids, water sufficient to reconstitute any concentrated skim milk or nonfat dry milk solids used.

§ 19.567 *Gorgonzola cheese; identity.* (a) Gorgonzola cheese is the food prepared from cow's milk or goat's milk or mixtures of these, and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It is characterized by the presence of bluish-green mold throughout the cheese. It is made in loaves weighing between 14 and 17 pounds. It contains not more than 42 percent moisture, and its solids contain not less than 50 percent milk fat, as determined by the methods prescribed in § 19.500 (c). It is not less than 90 days old.

(b) Milk, which may be pasteurized or clarified or both, which may be warmed, and which may be homogenized, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial green or blue coloring in a quantity which neutralizes any natural yellow coloring in the curd may be added. Sufficient rennet (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is cut into smaller portions and allowed to stand for a time. The mixed curd and whey is placed into forms permitting further drainage. While being placed in forms, spores of the mold Penicillium glaucum are added. The forms are turned several times during drainage. When sufficiently drained, the shaped curd is removed from the forms and salted with dry salt or brine. Perforations are then made in the shaped curd and it is held at a temperature of approximately 50° F., at 90 to 95 percent relative humidity, until the characteristic mold growth has developed. During storage the surface of the cheese is scraped, if necessary, to remove surface growth of undesirable microorganisms. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of gorgonzola cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk or goat's milk or mixtures of these.

(2) Such milk may be bleached by the use of benzoyl peroxide or mixture of benzoyl peroxide with potassium alum, calcium sulfate, and magnesium carbonate, but the weight of the benzoyl peroxide is not more than 0.002 percent of the weight of the milk being bleached, and the weight of the potassium alum, calcium sulfate, and magnesium carbonate, singly or combined, is not more than six times the weight of the benzoyl peroxide used. If milk is bleached in this manner, vitamin A is added to the curd in such quantity as to compensate for the vitamin A or its precursors destroyed in the bleaching process, and artificial coloring is not used.

(3) Such milk may be adjusted by separating part of the fat therefrom or by adding one or more of the following: (In the case of cow's milk) cream, cream which has been treated in the manner provided in subparagraph (2) of this paragraph, concentrated skim milk, nonfat dry milk solids; (in the case of goat's milk) the corresponding products obtained from goat's milk; water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk solids used.

§ 19.570 *Roquefort cheese, sheep's milk blue-mold cheese, blue-mold cheese from sheep's milk; identity.* (a) Roquefort cheese, sheep's milk blue-mold cheese, blue-mold cheese from sheep's milk, is the food prepared from sheep's milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It is characterized by the presence of bluish-green mold throughout the cheese. It contains not more than 45 percent moisture, and its solids contain not less than 50 percent milk fat, as determined by the methods prescribed in § 19.500 (c). It is not less than 60 days old.

(b) Milk, which may be pasteurized, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Sufficient rennet is added to set the milk to a semisolid mass. The mass is cut into smaller portions and allowed to stand for a time. The mixed curd and whey is placed in forms permitting further drainage of whey. Spores of the mold Penicillium roquefortii are added. The forms are turned several times during drainage. When sufficiently drained, the shaped curd is removed from the forms and salted with dry salt or brine. Perforations are then made in the shaped curd, and it is held at a temperature of approximately 50° F., with relative humidity of 90 to 95 percent, until the characteristic mold growth has developed. During storage the surface of the cheese is scraped, if necesary, to remove surface growth of undesirable microorganisms. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of roquefort cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section, the word "milk" means sheep's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto sheep's milk cream or skimmed sheep's milk.

§ 19.575 *Limburger cheese; identity.* (a) Limburger cheese is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 50 percent of moisture, and its solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in § 19.500 (c). If the milk used is not pasteurized, limburger cheese is held at a temperature of not less than 35° F. for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, is brought to a temperature of about 92° F. and subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Sufficient rennet (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is cut into cubes with sides approximately ½-inch long. After a few minutes the mass is stirred and heated, gradually raising the temperature to 96° F. to 98° F. The curd is then allowed to settle, most of the whey is drained off, and the remaining curd and whey dipped into molds. During drainage the curd may be pressed. It is turned at regular intervals. After drainage the curd is cut into pieces of desired size and dry-salted at intervals for 24 to 48 hours. The cheese is then cured with frequent applications of a weak brine solution to the surface, until the proper growth of surface-curing organisms is obtained. It is then wrapped and held in storage for development of as much additional flavor as is desired. When made from pasteurized milk, the milk is brought to a temperature of 89° F. to 90° F. after pasteurization. A culture of harmless lactic-acid-producing bacteria is added. Calcium chloride may be added, as to raw milk. The procedure then is the same as with raw milk, except that heating is to 94° F. After most of the whey is drained off, salt brine at a temperature of 66° F. to 70° F. is added, so that the pH of the curd is about 4.8. The mixed curd, whey, and brine is dipped into molds and the same procedure followed as when raw milk is used. Whether pasteurized or unpasteurized milk is used, a harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of limburger cheese, may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk solids used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F. for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction.

§ 19.580 *Monterey cheese, Monterey jack cheese; identity.* (a) Monterey cheese, Monterey jack cheese is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 44 percent of moisture, and its solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in § 19.500 (c).

(b) Milk, which is pasteurized, and which may be clarified, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Sufficient rennet (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is so cut, stirred, and heated with continued stirring, as to promote and regulate the separation of whey and curd. Part of the whey is drained off, and water or salt brine may be added. The curd is drained and placed in a muslin or sheeting cloth, formed into a ball, and pressed; or the curd is placed in a cheese hoop and pressed. Later, the cloth bandage is removed, and the cheese may be covered with paraffin or dipped in vegetable oil, and may have rice flour sprinkled on the surface. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of monterey cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk solids used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F. for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. Monterey cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 3 micrograms when tested by the method prescribed in § 19.500 (e).

§ 19.585 *High-moisture jack cheese; identity.* High-moisture jack cheese conforms to the definition and standard of identity prescribed for monterey cheese by § 19.580, except that its moisture content is not less than 44 percent, but less than 50 percent.

§ 19.590 *Provolone cheese, pasta filata cheese; identity.* (a) Provolone cheese, pasta filata cheese, is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It has a stringy texture, and may be made in several shapes. It contains not more than 45 percent of moisture, and its solids contain not less than 45 percent of milk fat, as determined by the methods prescribed in § 19.500 (c). If the milk used is not pasteurized, the cheese so made is held at a temperature of not less than 35° F. for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial blue or green coloring in a quantity which neutralizes any natural yellow coloring in the curd may be added. Sufficient rennet, rennet paste, or extract of rennet paste (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is cut, stirred, and heated so as to promote and regulate the separation of whey from the curd. The whey is drained off, and the curd is matted and cut, immersed in hot water, and kneaded and stretched until it is smooth and free from lumps. Then it is cut and molded. During the molding the curd is kept sufficiently warm to cause proper sealing of the surface. The molded curd is then firmed by immersion in cold water, salted in brine, and dried. Some shapes may be encased in ropes or twine before drying. Provolone cheese may be smoked. It is given some additional curing and covered with paraffin or similar wax. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of provolone cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk solids used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F. for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. Provolone cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 3 micrograms when tested by the method prescribed in § 19.500 (e).

(d) The name "Provolone cheese" ("Pasta filata cheese") may include the common name of the shape of the cheese, such as "Salami provolone." If provolone cheese is not smoked, the name includes the words "Not smoked."

§ 19.591 *Caciocavallo siciliano cheese; identity.* (a) Caciocavallo siciliano cheese is the food prepared from cow's milk or sheep's milk or goat's milk or mixtures of two or all of these and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It has a stringy texture, and is made in oblong shapes. It contains not more than 40 percent of moisture, and its solids contain not less than 42 percent milk fat, as determined by the methods prescribed in § 19.500 (c). It is cured for not less than 90 days at a temperature of not less than 35° F.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial blue or green coloring in a quantity which neutralizes any natural yellow coloring in the curd may be added. Sufficient rennet, rennet paste, or extract of rennet paste (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is cut, stirred, and heated so as to promote and regulate the separation of whey from the curd. The whey is drained off, and the curd is removed to another vat containing hot whey, in which it is soaked for several hours. This whey is withdrawn, the curd is allowed to mat, and is cut into blocks. These are washed in hot whey until the desired elasticity is obtained. The curd is removed from the vat, drained, pressed into oblong forms, dried, and salted in brine, and cured. It may be paraffined. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of caciocavallo siciliano cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section, the word "milk" means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids; (in the case of goat's milk) the corresponding products from goat's milk; (in the case of sheep's milk) the corresponding products from sheep's milk; water in a quantity sufficient to reconstitute any such concentrated or dried products used.

(d) When caciocavallo siciliano cheese is made solely from cow's milk, the name of such cheese is "Caciocavallo siciliano cheese." When made from sheep's milk or goat's milk or mixtures of these, or one or both of these with cow's milk, the name is followed by the words "made from ______," the blank being filled in with the name or names of the milks used, in order of predominance by weight.

§ 19.595 *Parmesan cheese, reggiano cheese; identity.* (a) Parmesan cheese, reggiano cheese, is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It is characterized by a granular texture and a hard and brittle rind. It grates readily. It contains not more than 32 percent of moisture, and its solids contain not less than 32 percent of milk fat, as determined by the methods prescribed in § 19.500 (c). It is cured for not less than 14 months.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Sufficient rennet (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. Harmless artificial coloring may be added. The mass is cut into pieces no larger than wheat kernels, heated, and stirred until the temperature reaches between 115° F. and 125° F. The curd is allowed to settle and is then removed from the kettle or vat, drained for a short time, placed in hoops, and pressed. The pressed curd is removed and salted in brine, or dry-salted. The cheese is cured in a cool, ventilated room. The rind of the cheese may be coated or colored. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of parmesan cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section, the word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk solids used.

§ 19.610 *Romano cheese; identity.* (a) Romano cheese is the food prepared from cow's milk or sheep's milk or goat's milk or mixtures of two or all of these and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It grates readily, and has a granular texture and a hard and brittle rind. It contains not more than 34 percent of moisture, and its solids contain not less than 38 percent of milk fat, as determined by the methods prescribed in § 19.500 (c). It is cured for not less than 5 months.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial blue or green coloring in a quantity which neutralizes any natural yellow coloring in the curd may be added. Rennet, rennet paste or extract of rennet paste (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is cut into particles no larger than corn kernels, stirred, and heated to a temperature of about 120° F. The curd is allowed to settle to the bottom of the kettle or vat, and is then removed and drained for a short time, packed in forms or hoops, and pressed. The pressed curd is salted by immersing in brine for about 24 hours and is then removed from the brine and the surface allowed to dry. It is then alternately rubbed with salt and washed at intervals. It may be perforated with needles. It is finally dry-cured. During curing it is turned and scraped. The surface may be rubbed with vegetable oil. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of romano cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section, the word "milk" means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids; (in the case of goat's milk) the corresponding products from goat's milk; (in the case of sheep's milk) the corresponding products from sheep's milk; water in a quantity sufficient to reconstitute any such concentrated or dried products used.

(d) When romano cheese is made solely from cow's milk the name of such cheese is "Romano cheese made from cow's milk" and may be preceded by the word "Vaccino" (or "Vacchino"); when made solely from sheep's milk, the name is "Romano cheese made from sheep's milk," and may be preceded by the word "Pecorina"; when made solely from goat's milk, the name is "Romano cheese made from goat's milk," and may be preceded by the word "Caprino"; and when a mixture of two or all of the milks specified in this section is used, the name of the cheese is "Romano cheese made from ______," the blank being filled in with the names of the milks used, in order of predominance by weight.

§ 19.615 *Asiago fresh cheese, asiago soft cheese; identity.* (a) Asiago fresh cheese, asiago soft cheese, is the food prepared from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 45 percent of moisture, and its solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in § 19.500 (c). It is cured for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial blue or green coloring in a quantity which neutralizes any natural yellow coloring in the curd may be added. Sufficient rennet (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is cut, stirred, and heated to promote and regulate separation of the whey from the curd. The whey is drained off. When the curd is sufficiently firm, it is removed from the kettle or vat, further drained for a short time, packed into hoops, and pressed. The pressed curd is salted in brine and cured in a well-ventilated room. During curing the surface of the cheese is occasionally rubbed with a vegetable oil. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of asiago fresh cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section, the word "milk" means cow's milk, which may be adjusted by separating part of the fat therefrom or by adding thereto one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids, water in a quantity sufficient to reconstitute any concentrated skim milk or nonfat dry milk solids used.

§ 19.620 *Asiago medium cheese; identity.* Asiago medium cheese conforms to the definition and standard of identity prescribed by § 19.615 for asiago fresh cheese, except that it contains not more than 35 percent moisture, its solids contain not less than 45 percent of milk fat, and it is cured for not less than 6 months.

§ 19.625 *Asiago old cheese; identity.* Asiago old cheese conforms to the definition and standard of identity prescribed by § 19.615 for asiago fresh cheese, except that it contains not more than 32 percent moisture, its solids contain not less than 42 percent of milk fat, and it is cured for not less than 1 year.

§ 19.635 *Cook cheese, koch kaese; identity.* (a) Cook cheese, koch kaese, is the food prepared from skim milk and other ingredients specified in this section by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 80 percent moisture as determined by the method therefor prescribed in § 19.500 (c). When tested for phosphatase by the method prescribed in § 19.500 (e), 0.25 gm. of cook cheese shows a phenol equivalent of not more than 3 micrograms.

(b) Skim milk, or the optional dairy ingredients specified in paragraph (c) of this section, which may be pasteurized, and which may be warmed, are subjected to the action of harmless lactic-acid-producing bacteria, present in such dairy ingredients or added thereto. A culture of a harmless white mold may be added. Sufficient rennet (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of milk) may be added to aid in setting the mix to a semisolid mass. The mass is cut, stirred, and heated, with continued stirring, so as to separate the curd and whey. The whey is drained from the curd, and the curd is cured for 2 or 3 days. It is then heated to a temperature of not less than 180° F. until the hot curd will drop from a ladle with a consistency like that of honey. The hot cheese is filled into packages and cooled. Pasteurized cream, salt, or caraway seed, or any mixture of two or more of these may be added.

(c) The optional dairy ingredients referred to in paragraph (b) of this section are: Skim milk or concentrated skim milk or nonfat dry milk solids or a mixture of any two or more of these, with water in a quantity not in excess of that sufficient to reconstitute any concentrated skim milk or nonfat dry milk solids used.

(d) For the purposes of this section, "skim milk" means cow's milk from which the milk fat has been separated.

§ 19.637 *Sap sago cheese; identity.* (a) Sap sago cheese is the food prepared from the skim milk of cows and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. It has a pale-green color, and is made in the shape of a truncated cone. It contains not more than 38 percent of moisture, as determined by the method prescribed in § 19.500 (c).

(b) Skim milk is allowed to become sour, and is heated to boiling temperature, with stirring. Cold buttermilk may be added. Sufficient sour whey is added to precipitate the casein. The curd is removed, spread out in boxes, and pressed, and while under pressure is allowed to drain and ferment. It is ripened for not less than 5 weeks. The ripened curd is dried and ground, salt and dried clover of the species Melilotus coerulea are added. The mixture is shaped into truncated cones. It is then cured for not less than 5 months.

§ 19.639 *Gammelost cheese; identity.* (a) Gammelost cheese is the food prepared from the skim milk of cows and the other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. It contains not more than 52 percent of moisture, as determined by the method prescribed in § 19.500 (c).

(b) Skim milk, which may be pasteurized, is subjected to the action of harmless lactic-acid-producing bacteria, present in such skim milk or added thereto. The development of acidity is continued until the skim milk coagulates to a semisolid mass. The mass is stirred and heated until a temperature of about 145° F. is reached, and is held at that temperature for not less than ½ hour. The whey is drained off and the curd removed and placed in forms and pressed. The shaped curd is placed in whey and heated for 3 or 4 hours. It is then removed from the whey and may again be pressed. It is then stored under conditions suitable for curing.

§ 19.650 *Hard cheeses; identity.* (a) The cheeses for which definitions and standards of identity are prescribed by this section are hard cheeses for which specifically applicable definitions and standards of identity are not prescribed by other sections of this part. They are made from milk and the other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. They contain not more than 39 percent of moisture, and their solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in § 19.500 (c). If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35° F. for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, with or without other harmless flavor-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet, rennet paste or extract of rennet paste (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is cut into small particles, stirred, and heated. The curd is separated from the whey, drained, and shaped into forms, and may be pressed. The curd is salted at some stage of the manufacturing process. The shaped curd may be cured. The rind may be coated with paraffin or rubbed with vegetable oil. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of hard cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used. Harmless flavor-producing microorganisms may be added, and curing may be conducted under suitable conditions for the development of biological curing agents.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom, or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids; (in the case of goat's milk) the corresponding products from goat's milk; (in the case of sheep's milk) the corresponding products from sheep's milk; water in

a quantity sufficient to reconstitute any concentrated or dried products used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F. for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. A hard cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 3 micrograms, when tested by the method prescribed in § 19.500 (e).

(d) The name of each hard cheese for which a definition and standard of identity is prescribed by this section is "Hard cheese," preceded or followed by:

(1) The specific common or usual name of such hard cheese, if any such name has become generally recognized therefor; or

(2) If no such specific common or usual name has become generally recognized therefor, an arbitrary or fanciful name which is not false or misleading in any particular.

(e) When milk other than cow's milk is used in whole or in part, the name of the cheese includes the statement "made from ____________," the blank being filled in with the name or names of the milk used, in order of predominance by weight.

§ 19.655 *Semisoft cheeses; identity; label statement of optional ingredients.* (a) The cheeses for which definitions and standards of identity are prescribed by this section are semisoft cheeses for which specifically applicable definitions and standards of identity are not prescribed by other sections of this part. They are made from milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. They contain more than 39 percent, but not more than 50 percent, of moisture, and their solids contain not less than 50 percent of milk fat, as determined by the methods prescribed in § 19.500 (c). If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35° F. for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria or other harmless flavor-producing bacteria, present in such milk or added thereto. Sufficient rennet, rennet paste, or extract of rennet paste (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. Harmless artificial coloring may be added. After coagulation the mass is so treated as to promote and regulate the separation of whey and curd. Such treatment may include one or more of the following: cutting, stirring, heating, dilution with water or brine. The whey, or part of it, is drained off, and the curd is collected and shaped. It may be placed in forms, and may be pressed. Harmless flavor-producing microorganisms may be added. It may be cured in a manner to promote the growth of biological curing agents. Salt may be added during the procedure. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of semisoft cheese may be added, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom, or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids; (in the case of goat's milk) the corresponding products from goat's milk; (in the case of sheep's milk) the corresponding products from sheep's milk; water in a quantity sufficient to reconstitute any concentrated or dried products used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F. for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. A semisoft cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 5 micrograms when tested by the method prescribed in § 19.500 (e).

(d) The name of each semisoft cheese for which a definition and standard of identity is prescribed by this section is "Semisoft cheese," preceded or followed by:

(1) The specific common or usual name of such semisoft cheese, if any such name has become generally recognized therefor; or

(2) If no such specific common or usual name has become generally recognized therefor, an arbitrary or fanciful name which is not false or misleading in any particular.

(e) When milk other than cow's milk is used in whole or in part, the name of the cheese includes the statement "made from ____________," the blank being filled in with the name or names of the milk used, in order of predominance by weight.

§ 19.660 *Semisoft part-skim cheeses; identity; label statement of optional ingredients.* (a) The cheeses for which definitions and standards of identity are prescribed by this section are semisoft part-skim cheeses for which specifically applicable definitions and standards of identity are not prescribed by other sections of this part. They are made from partly skimmed milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. They contain not more than 50 percent of moisture, and their solids contain not less than 45 percent, but less than 50 percent, of milk fat, as determined by the methods set forth in § 19.500 (c). If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35° F., for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria or other harmless flavor-producing bacteria, present in such milk or added thereto. Sufficient rennet, rennet paste, or extract of rennet paste (with or without purified calcium chloride, in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. Harmless artificial coloring may be added. After coagulation the mass is so treated as to promote and regulate the separation of whey and curd. Such treatment may include one or more of the following: Cutting, stirring, heating, dilution with water or brine. The whey, or part of it, is drained off, and the curd is collected and shaped. It may be placed in forms, and it may be pressed. Harmless flavor-producing microorganisms may be added. It may be cured in a manner to promote the growth of biological curing agents. Salt may be added during the procedure. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of semisoft part-skim cheese may be added in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids; (in the case of goat's milk) the corresponding products from goat's milk; (in the case of sheep's milk) the corresponding products from sheep's milk; water in a quantity sufficient to reconstitute any such concentrated or dried products used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F. for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. A semisoft part-skim cheese shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 5 micrograms when tested by the method prescribed in § 19.500 (e).

(d) The name of each semisoft part-skim cheese for which a definition and standard of identity is prescribed by this section is "Semisoft part-skim cheese," preceded or followed by:

(1) The specific common or usual name of such semisoft cheese, if any such name has become generally recognized therefor; or

(2) If no such specific common or usual name has become generally recognized therefor, an arbitrary or fanciful name which is not false or misleading in any particular.

(e) When milk other than cow's milk is used in whole or in part, the name of the cheese includes the statement "made from ____________," the blank being filled in with the name or names of the milk used, in order of predominance by weight.

§ 19.665 *Soft ripened cheeses; identity; label statement of optional ingredients.* (a) The cheeses for which definitions and standards of identity are prescribed by this section are soft ripened cheeses for which specifically applicable definitions and standards of identity are not prescribed by other sections of this part. They are made from milk and the other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. Their solids contain not less than 50 percent of milk fat, as determined by the method prescribed therefor in § 19.500 (c). If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35° F. for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria or other harmless flavor-producing bacteria, present in such milk or added thereto. Sufficient rennet, rennet paste, or extract of rennet paste (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. Harmless artificial coloring may be added. After coagulation the mass is so treated as to promote and regulate the separation of whey and curd. Such treatment may include one or more of the following: Cutting, stirring, heating, dilution with water or brine. The whey, or part of it, is drained off, and the curd is collected and shaped. It may be placed in forms, and may be pressed. Harmless flavor-producing microorganisms may be added. It is cured under conditions suitable for development of biological curing agents on the surface of the cheese, and the curing is conducted so that the cheese cures from the surface toward the center. Salt may be added during the procedure. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of soft ripened cheeses may be added, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids; (in the case of goat's milk) the corresponding products from goat's milk; (in the case of sheep's milk) the corresponding products from sheep's milk; water, in a quantity sufficient to reconstitute any such concentrated or dried products used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F. for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction.

(d) The name of each soft ripened cheese for which a definition and standard of identity is prescribed by this section is "Soft ripened cheese," preceded or followed by:

(1) The specific common or usual name of such soft ripened cheese, if any such name has become generally recognized therefor; or

(2) If no such specific common or usual name has become generally recognized therefor, an arbitrary or fanciful name which is not false or misleading in any particular.

(e) When milk other than cow's milk is used in whole or in part, the name of the cheese includes the statement "made from ____________," the blank being filled in with the name or names of the milk used, in order of predominance by weight.

§ 19.670 *Spiced cheeses; identity; label statement of optional ingredients.* (a) The cheeses for which definitions and standards of identity are prescribed by this section are spiced cheeses for which specifically applicable definitions and standards of identity are not prescribed by other sections of this part. They are made from milk and the other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. Their solids contain not less than 50 percent of milk fat as determined by the method therefor prescribed in § 19.500 (c). They contain one or a mixture of two or more spices, except any which singly or in combination with other ingredients simulate the flavor of a cheese of any age or variety, in an amount not less than 0.015 ounce per pound of cheese, and may contain spice oils. If the milk used is not pasteurized, the cheese so made is cured at a temperature of not less than 35° F. for not less than 60 days.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet, rennet paste, or extract of rennet (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is divided into smaller portions, and so handled by stirring, heating, and diluting with water or salt brine as to promote and regulate the separation of whey and curd. The whey is drained off. The curd is removed, and may be further drained. The curd is then shaped into forms, and may be pressed. At some time during the procedure, spices are added so as to be evenly distributed through the finished cheese. Spice oils may be added. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of spiced cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used. Harmless flavor-producing microorganisms may be added, and curing may be conducted under suitable conditions for the development of biological curing agents.

(c) For the purposes of this section:

(1) The word "milk" means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids; (in the case of goat's milk) the corresponding products from goat's milk; (in the case of sheep's milk) the corresponding products from sheep's milk; water in a quantity sufficient to reconstitute any such concentrated or dried products used.

(2) Milk shall be deemed to have been pasteurized if it has been held at a temperature of not less than 143° F. for a period of not less than 30 minutes, or for a time and at a temperature equivalent thereto in phosphatase destruction. Spiced cheeses shall be deemed not to have been made from pasteurized milk if 0.25 gm. shows a phenol equivalent of more than 3 micrograms, when tested by the method prescribed in § 19.500 (e).

(d) The name of each spiced cheese for which a definition and standard of identity is prescribed by this section is "Spiced cheese," preceded or followed by:

(1) The specific common or usual name of such spiced cheese, if any such name has become generally recognized therefor; or

(2) If no such specific common or usual name has become generally recognized therefor, an arbitrary or fanciful name which is not false or misleading in any particular.

(e) When milk other than cow's milk is used in whole or in part, the name of the cheese includes the statement "made from ____________," the blank being filled in with the name or names of the milk used, in order of predominance by weight.

§ 19.675 *Part-skim spiced cheeses; identity; label statement of optional ingredients.* Part-skim spiced cheeses conform to the definition and standard of identity, and are subject to the requirements for label statement of optional ingredients, prescribed for spiced cheeses by § 19.670, except that their solids contain less than 50 percent, but not less than 20 percent, of milk fat.

§ 19.680 *Hard grating cheeses; identity; label statement of optional ingredients.* (a) The cheeses for which definitions and standards of identity are prescribed by this section are hard grating cheeses for which specifically applicable definitions and standards of identity are not prescribed by other sections of this part. They are made from milk and the other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section. They contain not more than 34 percent of moisture, and their solids contain not less than 32 percent of milk fat, as determined by the methods prescribed in § 19.500 (c). Hard grating cheeses are cured for not less than 6 months.

(b) Milk, which may be pasteurized or clarified or both, and which may be warmed, is subjected to the action of harmless lactic-acid-producing bacteria or other harmless flavor-producing bacteria, present in such milk or added thereto. Sufficient rennet, rennet paste, or extract of rennet paste (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. Harmless artificial coloring may be added. The mass is cut into small particles, stirred, and heated. The curd is separated from the whey, drained, shaped into forms, pressed, salted, and cured. The rind may be colored or rubbed with vegetable oil or both. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of hard grating cheese may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) For the purposes of this section, the word "milk" means cow's milk or goat's milk or sheep's milk or mixtures of two or all of these. Such milk may be adjusted by separating part of the fat therefrom or (in the case of cow's milk) by adding one or more of the following: Cream, skim milk, concentrated skim milk, nonfat dry milk solids; (in the case of goat's milk) the corresponding products from goat's milk; (in the case of sheep's milk) the corresponding products from sheep's milk; water in a quantity sufficient to reconstitute any such concentrated or dried products used.

(d) The name of each hard grating cheese for which a definition and standard of identity is prescribed by this section is "Hard grating cheese," preceded or followed by:

(1) The specific common or usual name of such hard grating cheese, if any such name has become generally recognized therefor; or

(2) If no such specific common or usual name has become generally recognized therefor, an arbitrary or fanciful name which is not false or misleading in any particular.

(e) When milk other than cow's milk is used in whole or in part, the name of the cheese includes the statement "made from ___________," the blank being filled in with the name or names of the milk used, in order of predominance by weight.

§ 19.685 *Skim-milk cheese for manufacturing; identity.* (a) Skim-milk cheese for manufacturing is the food prepared from skim milk and other ingredients specified in this section, by the procedure set forth in paragraph (b) of this section, or by another procedure which produces a finished cheese having the same physical and chemical properties as the cheese produced when the procedure set forth in paragraph (b) of this section is used. It contains not more than 50 percent of moisture, as determined by the method therefor prescribed in § 19.500 (c). It is coated with blue-colored paraffin or other tightly adhering coating, colored blue.

(b) Skim milk or the optional dairy ingredients specified in paragraph (c) of this section, which may be pasteurized, and which may be warmed, are subjected to the action of harmless lactic-acid-producing bacteria, present in such milk or added thereto. Harmless artificial coloring may be added. Sufficient rennet (with or without purified calcium chloride in a quantity not more than 0.02 percent, calculated as anhydrous calcium chloride, of the weight of the milk) is added to set the milk to a semisolid mass. The mass is so cut, stirred, and heated with continued stirring, as to promote and regulate the separation of whey and curd. The whey is drained off, and the curd is matted into a cohesive mass. Proteins from the whey may be incorporated. The mass is cut into slabs which are so piled and handled as to promote the drainage of whey and the development of acidity. The slabs are then cut into pieces, which may be rinsed by pouring or sprinkling water over them, with free and continuous drainage; but the duration of such rinsing is so limited that only the whey on the surface of such pieces is removed. The curd is salted, stirred, further drained, and pressed into forms. A harmless preparation of enzymes of animal or plant origin capable of aiding in the curing or development of flavor of skim-milk cheese for manufacturing may be added during the procedure, in such quantity that the weight of the solids of such preparation is not more than 0.1 percent of the weight of the milk used.

(c) The optional dairy ingredients referred to in paragraph (b) of this section are: Skim milk or concentrated skim milk or nonfat dry milk solids or a mixture of any two or more of these, with water in a quantity not in excess of that sufficient to reconstitute any concentrated skim milk or nonfat dry milk solids used.

(d) For the purposes of this section, "skim milk" means cow's milk from which the milk fat has been separated.

§ 19.750 *Pasteurized process cheese; identity; label statement of optional ingredients.* (a) (1) Pasteurized process cheese is the food prepared by comminuting and mixing, with the aid of heat, one or more cheeses of the same or two or more varieties, except cream cheese, neufchatel cheese, cottage cheese, creamed cottage cheese, cook cheese, hard grating cheese, semisoft part-skim cheese, part-skim spiced cheese, and skim-milk cheese for manufacturing, with an emulsifying agent prescribed by paragraph (c) of this section, into a homogeneous plastic mass. One or more of the optional ingredients designated in paragraph (d) (1), (2), (3), (4), (5), and (6) of this section may be used.

(2) During its preparation, pasteurized process cheese is heated for not less than 30 seconds at a temperature of not less than 150° F. When tested for phosphatase by the method prescribed in § 19.500 (e), the phenol equivalent of 0.25 gm. of pasteurized process cheese is not more than 3 micrograms.

(3) (i) The moisture content of a pasteurized process cheese made from a single variety of cheese is not more than 1 percent greater than the maximum moisture content prescribed by the definition and standard of identity, if any there be, for the variety of cheese used; but in no case is more than 43 percent, except that the moisture content of pasteurized process washed curd cheese or pasteurized process colby cheese is not more than 40 percent; the moisture content of pasteurized process swiss cheese or pasteurized process gruyere cheese is not more than 44 percent; and the moisture content of pasteurized process limburger cheese is not more than 51 percent.

(ii) The fat content of the solids of a pasteurized process cheese made from a single variety of cheese is not less than the minimum prescribed by the definition and standard of identity, if any there be, for the variety of cheese used, but in no case is less than 47 percent; except that the fat content of the solids of pasteurized process swiss cheese is not less than 43 percent, and the fat content of the solids of pasteurized process gruyere cheese is not less than 45 percent.

(4) (i) The moisture content of a pasteurized process cheese made from two or more varieties of cheese is not more than 1 percent greater than the arithmetical average of the maximum moisture contents prescribed by the definitions and standards of identity, if any there be, for the varieties of cheese used; but in no case is the moisture content more than 43 percent, except that the moisture content of a pasteurized process cheese made from two or more of the varieties cheddar cheese, washed curd cheese, colby cheese, and granular cheese is not more than 40 percent, and the moisture content of a mixture of swiss cheese and gruyere cheese is not more than 44 percent.

(ii) The fat content of the solids of a pasteurized process cheese made from two or more varieties of cheese is not less than the arithmetical average of the minimum fat contents prescribed by the definitions and standards of identity, if any there be, for the varieties of cheese used, but in no case is less than 47 percent, except that the fat content of the solids of a pasteurized process gruyere cheese made from a mixture of swiss cheese and gruyere cheese is not less than 45 percent.

(5) Moisture and fat are determined by the methods prescribed in § 19.500 (c).

(6) The weight of each variety of cheese in a pasteurized process cheese made from two varieties of cheese is not less than 25 percent of the total weight of both, except that the weight of blue cheese, roquefort cheese, or gorgonzola cheese is not less than 10 percent of the total weight of both, and the weight of limburger cheese is not less than 5 percent of the total weight of both. The weight of each variety of cheese in a pasteurized process cheese made from three or more varieties of cheese is not less than 15 percent of the total weight of all, except that the weight of blue cheese, roquefort cheese, or gorgonzola cheese is not less than 5 percent of the total weight of all, and the weight of limburger cheese is not less than 3 percent of the total weight of all. These limits do not apply to the quantity of cheddar cheese, washed curd cheese,

colby cheese and granular cheese in mixtures which are designated as "American cheese" as prescribed in paragraph (e) (2) (ii) of this section. Such mixtures are considered as one variety of cheese for the purposes of this subparagraph.

(7) For the purposes of this section, cheddar cheese for manufacturing, washed curd cheese for manufacturing, colby cheese for manufacturing, granular cheese for manufacturing, brick cheese for manufacturing, and swiss cheese for manufacturing are considered as cheddar cheese, washed curd cheese, colby cheese, granular cheese, brick cheese, and swiss cheese, respectively.

(b) Pasteurized process cheese may be smoked, or the cheese or cheeses from which it is made may be smoked, before comminuting and mixing, or it may contain substances prepared by condensing or precipitating wood smoke.

(c) The emulsifying agent referred to in paragraph (a) of this section is one or any mixture of two or more of the following: Monosodium phosphate, disodium phosphate, dipotassium phosphate, trisodium phosphate, sodium metaphosphate (sodium hexametaphosphate), sodium acid pyrophosphate, tetrasodium pyrophosphate, sodium citrate, potassium citrate, calcium citrate, sodium tartrate, and sodium potassium tartrate, in such quantity that the weight of the solids of such emulsifying agents is not more than 3 percent of the weight of the pasteurized process cheese.

(d) The optional ingredients referred to in paragraph (a) of this section are:

(1) An acidifying agent consisting of one or any mixture of two or more of the following: A vinegar, lactic acid, citric acid, acetic acid, and phosphoric acid, in such quantity that the pH of the pasteurized process cheese is not below 5.3.

(2) Cream, in such quantity that the weight of the fat derived therefrom is less than 5 percent of the weight of the pasteurized process cheese.

(3) Water.

(4) Salt.

(5) Harmless artificial coloring.

(6) Spices or flavorings, other than any which singly or in combination with other ingredients simulate the flavor of a cheese of any age or variety.

(e) The name of a pasteurized process cheese for which a definition and standard of identity is prescribed by this section is as follows:

(1) In case it is made from a single variety of cheese, its name is "Pasteurized process ------------ cheese," the blank being filled in with the name of the variety of cheese used.

(2) In case it is made from two or more varieties of cheese, its name is "Pasteurized process ------------ and ------------ cheese," or "Pasteurized process -------- blended with -------- cheese," or "Pasteurized process blend of ---------- and ---------- cheese," the blanks being filled in with the names of the varieties of cheeses used, in order of predominance by weight; except that:

(i) In case it is made from gruyere cheese and swiss cheese, and the weight of gruyere cheese is not less than 25 percent of the weight of both, it may be designated "Pasteurized process gruyere cheese"; and

(ii) In case it is made of cheddar cheese, washed curd cheese, colby cheese, or granular cheese or any mixture of two or more of these, it may be designated "Pasteurized process American cheese"; or when cheddar cheese, washed curd cheese, colby cheese, or granular cheese or any mixture of two or more of these is combined with other varieties of cheese in the cheese ingredient any of such cheeses or such mixture may be designated as "American cheese."

(f) (1) If the pasteurized process cheese is smoked, or made from cheeses which have been smoked, the word "smoked" shall precede or follow the name of the pasteurized process cheese or name of the cheese ingredient which was smoked.

(2) If it contains a substance prepared by condensing or precipitating wood smoke, the label shall bear the term "with added ------------," the blank being filled in with the common or usual name of such ingredient.

(3) If it contains spice, the label shall bear the term "spiced" or "spice added" or "with added spice," or in lieu of the word "spice" the common or usual name of the spice.

(4) If it contains added flavoring, the label shall bear the term "flavoring added," "with added flavoring," or "flavored with ------------," the blank being filled in with the common or usual name of the flavoring; if the flavoring is artificial, the word "artificial" shall precede the word "flavoring," or the word "artificially" shall precede the term "flavored with ------------."

(5) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements herein specified, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 19.751 *Pasteurized blended cheese; identity; label statement of optional ingredients.* (a) Pasteurized blended cheese conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for pasteurized process cheese by § 19.750, except that:

(1) In mixtures of two or more cheeses, cream cheese or neufchatel cheese may be used.

(2) None of the ingredients prescribed or permitted for pasteurized process cheese by § 19.750 (c) and (d) (1) is used.

(3) In case of mixtures of two or more cheeses containing cream cheese or neufchatel cheese, the moisture content is not more than the arithmetical average of the maximum moisture contents prescribed by the definitions and standards of identity for the varieties of cheeses blended, for which such limits have been prescribed.

(4) The word "process" is replaced by the word "blended" in the name prescribed by § 19.750 (e).

§ 19.755 *Pasteurized process cheese with fruits, vegetables, or meats; identity; label statement of optional ingredients.* (a) Unless a definition and standard of identity specifically applicable is established by another section of this part, a pasteurized process cheese with fruits, vegetables, or meats or mixture of these is a food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for pasteurized process cheese by § 19.750, except that:

(1) Its moisture content may be 1 percent more, and the milk fat content of its solids may be 1 percent less, than the limits prescribed by § 19.750 for moisture and fat in the corresponding pasteurized process cheese.

(2) It contains one or any mixture of two or more of the following: Any properly prepared cooked, canned, or dried fruit; any properly prepared cooked, canned, or dried vegetable; any properly prepared cooked or canned meat.

(3) When the added fruits, vegetables, or meats contain fat, the method prescribed for the determination of fat by § 19.500 (c) is not applicable.

(b) The name of a pasteurized process cheese with fruits, vegetables, or meats is the name prescribed by § 19.750 for the applicable pasteurized process cheese, followed by the term "with ----------," the blank being filled in with the common or usual name or names of the fruits, vegetables, or meats used, in order of predominance by weight.

§ 19.760 *Pasteurized process pimento cheese; identity.* (a) Pasteurized process pimento cheese is the food which conforms to the definition and standard of identity for pasteurized process cheese with fruits, vegetables, or meats, except that:

(1) Its moisture content is not more than 41 percent, and the fat content of its solids is not less than 49 percent.

(2) The cheese ingredient is cheddar cheese, washed curd cheese, colby cheese, granular cheese or any mixture of two or more of these in any proportion.

(3) For the purposes of this section, cheddar cheese for manufacturing, washed curd cheese for manufacturing, colby cheese for manufacturing, and granular cheese for manufacturing shall be considered as cheddar cheese, washed curd cheese, colby cheese, and granular cheese, respectively.

(4) The only fruit, vegetable, or meat ingredient is pimentos in such quantity that the weight of the solids thereof is not less than 0.2 percent of the weight of the finished pasteurized process pimento cheese.

(5) The optional ingredients designated in § 19.750 (b) and (d) (6) are not used.

§ 19.763 *Pasteurized blended cheese with fruits, vegetables, or meats; identity; label statement of optional ingredients.* (a) Pasteurized blended cheese with fruits, vegetables, or meats or mixtures of these is the food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for pasteurized blended cheese by § 19.751, except that:

(1) Its moisture content may be 1 percent more, and the milk fat content of its solids may be 1 percent less, than the limits prescribed by § 19.751 for moisture and milk fat in the corresponding pasteurized blended cheese.

(2) It contains one or any mixture of two or more of the following: Any properly prepared cooked, canned, or dried fruit; any properly prepared cooked, canned, or dried vegetable; any properly prepared cooked or canned meat.

(3) When the added fruits, vegetables, or meats contain fat, the method prescribed for the determination of fat by § 19.500 (c) is not applicable.

(b) The name of a pasteurized blended cheese with fruits, vegetables, or meats is the name prescribed by § 19.751 for the applicable pasteurized blended cheese, followed by the term "with __________," the blank being filled in with the common or usual name or names of the fruits, vegetables, or meats used, in order of predominance by weight.

§ 19.765 *Pasteurized process cheese food; identity; label statement of optional ingredients.* (a) (1) A pasteurized process cheese food is the food prepared by comminuting and mixing, with the aid of heat, one or more of the optional cheese ingredients prescribed in paragraph (c) of this section, with one or more of the optional dairy ingredients prescribed in paragraph (d) of this section, into a homogeneous plastic mass. One or more of the optional ingredients specified in paragraph (e) of this section may be used.

(2) During its preparation, a pasteurized process cheese food is heated for not less than 30 seconds, at a temperature of not less than 150° F. When tested for phosphatase by the method prescribed in §19.500 (e), the phenol equivalent of 0.25 gm. of pasteurized process cheese food is not more than 3 micrograms.

(3) The moisture content of a pasteurized process cheese food is not more than 44 percent, and the fat content is not less than 23 percent.

(4) Moisture and fat are determined by the methods prescribed in § 19.500 (c), except that in determining moisture the loss in weight which occurs in drying for 5 hours, under the conditions prescribed in such method, is taken as the weight of moisture.

(5) The weight of the cheese ingredient prescribed by subparagraph (1) of this paragraph constitutes not less than 51 percent of the weight of the finished pasteurized process cheese food.

(6) The weight of each variety of cheese in a pasteurized process cheese food made with two varieties of cheese is not less than 25 percent of the total weight of both, except that the weight of blue cheese, roquefort cheese, gorgonzola cheese, or limburger cheese is not less than 10 percent of the total weight of both. The weight of each variety of cheese in a pasteurized process cheese food made with three or more varieties of cheese is not less than 15 percent of the total weight of all, except that the weight of blue cheese, roquefort cheese, gorgonzola cheese, or limburger cheese is not less than 5 percent of the total weight of all. These limits do not apply to the quantity of cheddar cheese, washed curd cheese, colby cheese, and granular cheese in mixtures which are designated as "American cheese" as prescribed in paragraph (f) (6) of this section. Such mixtures are considered as one variety of cheese for the purposes of this subparagraph.

(7) For the purposes of this section, cheddar cheese for manufacturing, washed curd cheese for manufacturing, colby cheese for manufacturing, granular cheese for manufacturing, brick cheese for manufacturing, and swiss cheese for manufacturing are considered as cheddar cheese, washed curd cheese, colby cheese, granular cheese, brick cheese, and swiss cheese, respectively.

(b) Pasteurized process cheese food may be smoked, or the cheese or cheeses from which it is made may be smoked, before comminuting and mixing, or it may contain substances prepared by condensing or precipitating wood smoke.

(c) The optional cheese ingredients referred to in paragraph (a) of this section are one or more cheeses of the same or two or more varieties, except cream cheese, neufchatel cheese, cottage cheese, creamed cottage cheese, cook cheese, and skim-milk cheese for manufacturing, and except that hard grating cheese, semisoft part skim cheese, and part-skim spiced cheese are not used, alone or in combination with each other, as the cheese ingredient.

(d) The optional dairy ingredients referred to in paragraph (a) of this section are cream, milk, skim milk, cheese whey, or any mixture of two or more of these, or any of the foregoing from which part of the water has been removed, and albumin from cheese whey and skim-milk cheese for manufacturing.

(e) The other optional ingredients referred to in paragraph (a) of this section are:

(1) An emulsifying agent consisting of one or any mixture of two or more of the following: Monosodium phosphate, disodium phosphate, dipotassium phosphate, trisodium phosphate, sodium metaphosphate (sodium hexametaphosphate), sodium acid pyrophosphate, tetrasodium pyrophosphate, sodium citrate, potassium citrate, calcium citrate, sodium tartrate, and sodium potassium tartrate, in such quantity that the weight of the solids of such emulsifying agent is not more than 3 percent of the weight of the pasteurized process cheese food.

(2) An acidifying agent consisting of one or any mixture of two or more of the following: A vinegar, lactic acid, citric acid, acetic acid, and phosphoric acid, in such quantity that the pH of the pasteurized process cheese food is not below 5.0.

(3) Water.

(4) Salt.

(5) Harmless artificial coloring.

(6) Spices or flavorings other than any which singly or in combination with other ingredients simulate the flavor of cheese of any age or variety.

(f) The label of a pasteurized process cheese food shall bear the common or usual names of the optional ingredients used, as specified in paragraphs (c), (d), and (e) (1), (2), (3), and (4) of this section, and:

(1) If the pasteurized process cheese food is smoked, or made from cheeses which have been smoked, the word "smoked" shall precede or follow the name of the pasteurized process cheese food or the name of the cheese ingredient which was smoked.

(2) If it contains a substance prepared by condensing or precipitating wood smoke, the label shall bear the statement "with added ____________," the blank being filled in with the common or usual name of such ingredient.

(3) If it contains spice, the label shall bear the statement "spiced" or "spice added" or "with added spice," or in lieu of the word "spice" the common or usual name of the spice used.

(4) If it contains added flavoring, the label shall bear the statement "flavoring added," "with added flavoring," or "flavored with ____________," the blank being filled in with the common or usual name of the flavoring used; if the flavoring is artificial, the word "artificial" shall precede the word "flavoring" or the word "artificially" shall precede the statement "flavored with ____________."

(5) If it contains added artificial coloring, the label shall bear the statement "artificially colored" or "contains artificial color."

(6) If the cheese ingredient contains cheddar cheese, washed curd cheese, colby cheese, granular cheese or any mixture of two or more of these, such cheese or such mixture may be designated as "American cheese."

(g) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements herein specified, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 19.770 *Pasteurized process cheese food with fruits, vegetables, or meats; identity; label statement of optional ingredients.* (a) Pasteurized process cheese food with fruits, vegetables, or meats, or mixtures of these is the food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for pasteurized process cheese food by § 19.765, except that:

(1) Its milk fat content is not less than 22 percent.

(2) It contains one or any mixture of two or more of the following: Any properly prepared cooked, canned, or dried fruit; any properly prepared cooked, canned, or dried vegetable; any properly prepared cooked or canned meat.

(3) When the added fruits, vegetables, or meats contain fat, the method prescribed for the determination of fat by § 19.500 (c) is not applicable.

(b) The name of a pasteurized process cheese food with fruits, vegetables, or meats is "Pasteurized process cheese food with ___________," the blank being filled in with the common or usual name or names of the fruits, vegetables, or meats used, in order of predominance by weight.

(c) If the only vegetable ingredient is pimento, and no meat or fruit ingredient is used, the weight of the solids of such pimentos is not less than 0.2 percent of the weight of the finished food. The name of this food is "Pimento pasteurized process cheese food" or "Pasteurized process pimento cheese food."

§ 19.775 *Pasteurized process cheese spread; identity; label statement of optional ingredients.* (a) (1) Pasteurized process cheese spread is the food prepared by comminuting and mixing, with the aid of heat, one or more of the optional cheese ingredients prescribed in paragraph (c) of this section, with or without one or more of the optional dairy ingredients prescribed in paragraph (d) of this section, with one or more of the emulsifying agents prescribed in paragraph (e) of this section, and with or without one or more of the optional ingredients prescribed by paragraph (f) of this section, into a homogeneous plastic mass, which is spreadable at 70° F.

(2) During its preparation, a pasteurized process cheese spread is heated for not less than 30 seconds at a temperature of not less than 150° F. When tested for phosphatase by the method prescribed in § 19.500 (e) the phenol equivalent of 0.25 gm. of pasteurized process cheese spread is not more than 3 micrograms.

(3) The moisture content of a pasteurized process cheese spread is more than 44 percent but not more than 60 percent, and the milk fat content is not less than 20 percent.

(4) Moisture and fat are determined by the methods prescribed in § 19.500 (c), except that in determining moisture the loss in weight which occurs in drying for 5 hours under the conditions prescribed in such method, is taken as the weight of the moisture.

(5) The weight of the cheese ingredient referred to in subparagraph (1) of this paragraph constitutes not less than 51 percent of the weight of the pasteurized process cheese spread.

(6) The weight of each variety of cheese in a pasteurized process cheese spread made with two varieties of cheese is not less than 25 percent of the total weight of both, except that the weight of blue cheese, roquefort cheese, gorgonzola cheese, or limburger cheese is not less than 10 percent of the total weight of both. The weight of each variety of cheese in a pasteurized process cheese spread made with three or more varieties of cheese is not less than 15 percent of the total weight of all, except that the weight of blue cheese, roquefort cheese, gorgonzola cheese, or limburger cheese is not less than 5 percent of the total weight of all. These limits do not apply to the quantity of cheddar cheese, washed curd cheese, colby cheese, and granular cheese in mixtures which are designated as "American cheese" as prescribed in paragraph (g) (6) of this section. Such mixtures are considered as one variety of cheese for the purposes of this subparagraph.

(7) For the purposes of this section, cheddar cheese for manufacturing, washed curd cheese for manufacturing, colby cheese for manufacturing, granular cheese for manufacturing, brick cheese for manufacturing, and swiss cheese for manufacturing are considered as cheddar cheese, washed curd cheese, colby cheese, granular cheese, brick cheese, and swiss cheese, respectively.

(b) Pasteurized process cheese spread may be smoked, or the cheese or cheeses from which it is made may be smoked, before comminuting and mixing, or it may contain substances prepared by condensing or precipitating wood smoke.

(c) The optional cheese ingredients referred to in paragraph (a) of this section are one or more cheeses of the same or two or more varieties, except that skim-milk cheese for manufacturing may not be used, and except that cream cheese, neufchatel cheese, cottage cheese, creamed cottage cheese, cook cheese, hard grating cheese, semisoft part-skim cheese, and part-skim spiced cheese are not used, alone or in combination with each other, as the cheese ingredient.

(d) The optional dairy ingredients referred to in paragraph (a) of this section are cream, milk, skim milk, cheese whey, or any mixture of two or more of these, or any of the foregoing from which part of the water has been removed, and albumin from cheese whey, and skim-milk cheese for manufacturing.

(e) The emulsifying agents prescribed in paragraph (a) of this section are one or any mixture of two or more of the following: Monosodium phosphate, disodium phosphate, dipotassium phosphate, trisodium phosphate, sodium metaphosphate (sodium hexametaphosphate), sodium acid pyrophosphate, tetrasodium pyrophosphate, sodium citrate, potassium citrate, calcium citrate, sodium tartrate, and sodium potassium tartrate, in such quantity that the weight of the solids of such emulsifying agent is not more than 3 percent of the weight of the pasteurized process cheese spread.

(f) The other optional ingredients referred to in paragraph (a) of this section are:

(1) One or any mixture of two or more of the following: Carob bean gum, gum karaya, gum tragacanth, guar gum, gelatin, carboxy-methylcellulose, carrageen, oatgum, algin (sodium alginate), and algin derivative (propylene glycol ester of alginic acid). The total weight of such substances is not more than 0.8 percent of the weight of the finished food.

(2) An acidifying agent consisting of one or any mixture of two or more of the following: A vinegar, lactic acid, citric acid, acetic acid, and phosphoric acid, in such quantity that the pH of the pasteurized process cheese spread is not below 4.0.

(3) A sweetening agent consisting of one or any mixture of two or more of the following: Sugar, dextrose, corn sugar, corn sirup, corn sirup solids, glucose sirup, glucose sirup solids, maltose, malt sirup, and hydrolyzed lactose, in a quantity necessary for seasoning.

(4) Water.

(5) Salt.

(6) Harmless artificial coloring.

(7) Spices or flavorings other than any which singly or in combination with other ingredients simulate the flavor of a cheese of any age or variety.

(g) The label of a pasteurized process cheese spread shall bear the common or usual names of the optional ingredients used, as specified in paragraphs (c), (d), (e), and (f) (1), (2), (3), (4), and (5) of this section, except that carob bean gum, gum karaya, gum tragacanth, guar gum, and oat gum may be designated as "vegetable gum," and:

(1) If the pasteurized process cheese spread is smoked, or made from cheeses which have been smoked, the word "smoked" shall precede or follow the name of the pasteurized process cheese spread or name of the cheese ingredient which was smoked.

(2) If it contains a substance prepared by condensing or precipitating wood smoke, the label shall bear the statement "with added ______________," the blank being filled in with the common or usual name of such ingredient.

(3) If it contains spice, the label shall bear the statement "spiced" or "spice added" or "with added spice" or in lieu of the word "spice" the common or usual name of the spice used.

(4) If it contains added flavoring, the label shall bear the statement "flavoring added," "with added flavoring," or "flavored with ____________," the blank being filled in with the common or usual name of the flavoring used; and if the flavoring is artificial, the word "artificial" shall precede the word "flavoring" or the word "artificially" shall precede the statement "flavored with ____________."

(5) If it contains added artificial coloring, the label shall bear the statement "artificially colored" or "contains artificial color."

(6) If the cheese ingredient contains cheddar cheese, washed curd cheese, colby cheese, granular cheese or any mixture of two or more of these, such cheese or such mixture may be designated as "American cheese."

(7) If an optional acidifying agent is used so that the pH of the finished food is less than 5.0, there shall appear after its name the words "a chemical preservative." In case vinegar is the only acidifying agent added it shall be considered to be acetic acid when the pH of the finished food is less than 5.0. In case vinegar and other acidifying agents are used and the pH of the finished food is less than 5.0, the name of the acidifying agents other than vinegar shall be followed by the statement "a chemical preservative."

(h) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements herein specified, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 19.776 *Pasteurized cheese spread; identity; label statement of optional ingredients.* Pasteurized cheese spread is the food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for pasteurized process cheese spread by § 19.775, except that no emulsifying agent as prescribed by § 19.775 (e) is used.

§ 19.780 *Pasteurized process cheese spread with fruits, vegetables, or meats; identity; label statement of optional ingredients.* (a) Pasteurized process cheese spread with fruits, vegetables, or meats or mixtures of these is the food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for pasteurized process cheese spread by § 19.775, except that:

(1) It contains one or any mixture of two or more of the following: Any properly prepared cooked, canned, or dried fruit; any properly prepared cooked, canned, or dried vegetable; any properly prepared cooked or canned meat.

(2) When the added fruits, vegetables, or meats contain fat, the method prescribed for the determination of fat by § 19.500 (c) is not applicable.

(b) The name of a pasteurized process cheese spread with fruits, vegetables, or meats is "Pasteurized process cheese spread with ------------," the blank being filled in with the name or names of the fruits, vegetables, or meats used, in order of predominance by weight.

§ 19.781 *Pasteurized cheese spread with fruits, vegetables, or meats; identity; label statement of optional ingredients.* (a) Pasteurized cheese spread with fruits, vegetables, or meats or mixtures of these is the food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for pasteurized cheese spread by § 19.776, except that:

(1) It contains one or any mixture of two or more of the following: Any properly prepared cooked, canned, or dried fruit; any properly prepared cooked, canned, or dried vegetable; any properly prepared cooked or canned meat.

(2) When the added fruits, vegetables, or meats contain fat, the method prescribed for the determination of fat by § 19.500 (c) is not applicable.

(b) The name of a pasteurized cheese spread with fruits, vegetables, or meats is "Pasteurized cheese spread with ------------," the blank being filled in with the name or names of the fruits, vegetables, or meats used, in order of predominance by weight.

§ 19.782 *Cream cheese with other foods; identity; label statement of optional ingredients.* (a) Cream cheese with other foods is the class of foods each of which is prepared by mixing, with or without the aid of heat, cream cheese with one or a mixture of two or more properly prepared foods (except other cheeses), such as fresh, cooked, canned, or dried fruits or vegetables; cooked or canned meats; relishes, pickles, or other foods suitable for blending with cream cheese. The amount of the added food or foods must be sufficient to so differentiate the mixture that it does not simulate cream cheese. The mixture may also contain:

(1) One or any mixture of two or more of the following optional ingredients: Gum karaya, gum tragacanth, carob bean gum, gelatin, guar gum, carboxymethylcellulose, carrageen, oat gum, algin (sodium alginate), algin derivative (propylene glycol ester of alginic acid). The total quantity of any such substances, including that contained in the cream cheese, is not more than 0.8 percent by weight of the finished food.

(2) Artificial coloring, unless such addition conceals damage or inferiority or makes the finished food appear better or of greater value than it is.

(b) No water other than that contained in the added food ingredients is used, but the moisture content of the mixture in no case is more than 60 percent. The milk fat is not less than 33 percent of the percent by weight of the cream cheese used, but in no case is it less than 27 percent of the finished food. Moisture and fat are determined by the methods prescribed in § 19.500 (c), except that when the added food contains fat the method prescribed for the determination of fat is not applicable.

(c) The name of the food is "Cream cheese with ————" or "Cream cheese and ————," the blank being filled with the common names of the foods added, in order of predominance by weight.

(d) The label shall bear the name of the optional water-retaining ingredients used, except that carob bean gum, gum karaya, gum tragacanth, guar gum, and oat gum, or mixture of these may be named as "vegetable gum" or "vegetable gums," as the case may be.

(e) If artificial coloring is used, the label shall bear the statement "artificially colored," except that if the food added to the cream cheese is the only portion artificially colored, the label shall bear the statement "———— artificially colored," the blank being filled in with the name or names of the food so colored.

(f) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements herein specified, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 19.783 *Pasteurized neufchatel cheese spread with other foods; identity; label statement of optional ingredients.* (a) (1) Pasteurized neufchatel cheese spread with other foods is the class of foods each of which is prepared by mixing, with the aid of heat, neufchatel cheese with one or a mixture of two or more properly prepared foods (except other cheeses), such as fresh, cooked, canned, or dried fruits or vegetables; cooked or canned meats; relishes, pickles, or other foods suitable for blending with neufchatel cheese. It may contain one or any mixture of two or more of the optional ingredients named in paragraph (b) of this section. The amount of the added food or foods must be sufficient to so differentiate the blend that it does not simulate neufchatel cheese. It is spreadable at 70° F.

(2) During its preparation the mixture is heated for not less than 30 seconds at a temperature of not less than 150° F. When tested for phosphatase by the method prescribed in § 19.500 (e), the phenol equivalent of 0.25 gram of such food is not more than 3 micrograms.

(3) (i) No water other than that contained in the ingredients used is added to this food, but the moisture content in no case is more than 65 percent.

(ii) The milk fat is not less than 20 percent by weight of the finished food.

(b) The optional ingredients referred to in paragraph (a) of this section are:

(1) One or any mixture of two or more of the following: Gum karaya, gum tragacanth, carob bean gum, gelatin, algin (sodium alginate), algin derivative (propylene glycol ester of alginic acid), guar gum, carboxymethylcellulose, carrageen, oat gum. The total quantity of any such substances, including that contained in the neufchatel cheese, is not more than 0.8 percent by weight of the finished food.

(2) Artificial coloring, unless such addition conceals damage or inferiority or makes the finished food appear better or of greater value than it is.

(3) An acidifying agent consisting of one or a mixture of two or more of the following: A vinegar, acetic acid, lactic acid, citric acid, phosphoric acid.

(4) A sweetening agent consisting of one or a mixture of two or more of the following: Sugar, dextrose, corn sirup, corn sirup solids, glucose sirup, glucose sirup solids, maltose, malt sirup, hydrolyzed lactose.

(5) Cream, milk, skim milk, cheese whey or any mixture of two or more of these, or any of the foregoing from which part of the water has been removed, and albumin from cheese whey.

(c) The name of the food is "Pasteurized neufchatel cheese spread with ---------------" or "Pasteurized neufchatel cheese spread and ------------," the blank being filled with the common names of the foods added, in order of predominance by weight.

(d) The label shall bear the names of any of the optional ingredients used designated in paragraph (b) (1), (3), (4), and (5) of this section, except that carob bean gum, gum karaya, gum tragacanth, guar gum, and oat gum or mixtures of these may be named as "vegetable gum" or "vegetable gums," as the case may be.

(e) (1) If artificial coloring is used, the label shall bear the statement "artificially colored," except that if the food added to the neufchatel cheese is the only portion artificially colored, the label shall bear the statement "------------ artificially colored," the blank being filled in with the name or names of the foods so colored.

(2) If an optional acidifying agent is used so that the pH of the finished food is less than 4.2, there shall appear after its name the words "a chemical preservative." In case vinegar is the only acidifying agent added, it shall be considered to be acetic acid when the pH of the finished food is less than 4.2. In case vinegar and other acidifying agents are used and the pH of the finished food is less than 4.2, only the name or names of the acidifying agents other than vinegar

shall be followed by the statement "a chemical preservative."

(f) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements herein specified, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 19.785 *Cold-pack cheese, club cheese, comminuted cheese; identity; label statement of optional ingredients.* (a) (1) Cold-pack cheese, club cheese, comminuted cheese, is the food prepared by comminuting, without the aid of heat, one or more cheeses of the same or two or more varieties, except cream cheese, neufchatel cheese, cottage cheese, creamed cottage cheese, hard grating cheese, semisoft part-skim cheese, part-skim spiced cheese, and skim-milk cheese for manufacturing, into a homogeneous plastic mass. One or more of the optional ingredients designated in paragraph (c) of this section may be used.

(2) All cheeses used in a cold-pack cheese are made from pasteurized milk or are held for not less than 60 days at a temperature of not less than 35° F. before being comminuted.

(3) (i) The moisture content of a cold-pack cheese made from a single variety of cheese is not more than the maximum moisture content prescribed by the definition and standard of identity, if any there be, for the variety of cheese used. If there is no applicable definition and standard of identity, or if such standard contains no provision as to maximum moisture content, no water is used in the preparation of the cold-pack cheese.

(ii) The fat content of the solids of a cold-pack cheese made from a single variety of cheese is not less than the minimum prescribed by the definition and standard of identity, if any there be, for the variety of cheese used, but in no case is less than 47 percent, except that the fat content of the solids of cold-pack swiss cheese is not less than 43 percent, and the fat content of the solids of cold-pack gruyere cheese is not less than 45 percent.

(4) (i) The moisture content of a cold-pack cheese made from two or more varieties of cheese is not more than the arithmetical average of the maximum moisture contents prescribed by the definitions and standards of identity, if any there be, for the varieties of cheese used, but in no case is the moisture content more than 42 percent, except that the moisture content of a cold-pack cheese made from two or more of the varieties cheddar cheese, washed curd cheese, colby cheese, and granular cheese is not more than 39 percent.

(ii) The fat content of the solids of a cold-pack cheese made from two or more varieties of cheese is not less than the arithmetical average of the minimum percent of fat prescribed by the definitions and standards of identity, if any there be, for the varieties of cheese used, but in no case is less than 47 percent, except that the fat content of the solids of a cold-pack cheese made from swiss cheese and gruyere cheese is not less than 45 percent.

(5) Moisture and fat are determined by the methods prescribed in § 19.500 (c).

(6) The weight of each variety of cheese in a cold-pack cheese made from two varieties of cheese is not less than 25 percent of the total weight of both, except that the weight of blue cheese, roquefort cheese, or gorgonzola cheese is not less than 10 percent of the total weight of both, and the weight of limburger cheese is not less than 5 percent of the total weight of both. The weight of each variety of cheese in a cold-pack cheese made from three or more varieties of cheese is not less than 15 percent of the total weight of all, except that the weight of blue cheese, roquefort cheese, or gorgonzola cheese is not less than 5 percent of the total weight of all, and the weight of limburger cheese is not less than 3 percent of the total weight of all. These limits do not apply to the quantity of cheddar cheese, washed curd cheese, colby cheese, and granular cheese in mixtures which are designated as "American cheese" as prescribed in paragraph (d) (2) of this section. Such mixtures are considered as one variety of cheese for the purpose of this subparagraph.

(b) Cold-pack cheese may be smoked, or the cheese or cheeses from which it is made may be smoked, before comminuting and mixing, or it may contain substances prepared by condensing or precipitating wood smoke.

(c) The optional ingredients referred to in paragraph (a) of this section are:

(1) An acidifying agent consisting of one or any mixture of two or more of the following: A vinegar, lactic acid, citric acid, acetic acid, and phosphoric acid, in such quantity that the pH of the finished cold-pack cheese is not below 4.5. For the purposes of this section vinegar is considered to be acetic acid.

(2) Water.

(3) Salt.

(4) Harmless artificial coloring.

(5) Spices or flavorings, other than any which singly or in combination with other ingredients simulate the flavor of a cheese of any age or variety.

(d) (1) The name of a cold-pack cheese for which a definition and standard of identity is prescribed by this section is "Cold-pack ------------ cheese" or "------------ club cheese" or "Comminuted ------------ cheese," the blanks being filled in with the name or names of the varieties of cheese used, in order of predominance by weight.

(2) If the cold-pack cheese is made of cheddar cheese, washed curd cheese, colby cheese, or granular cheese or any mixture of two or more of these, it may be designated "Cold-pack American cheese"; or when cheddar cheese, washed curd cheese, colby cheese, or granular cheese or any mixture of two or more of these is combined with other varieties of cheese in the cheese ingredient any of such cheeses or such mixture may be designated as "American cheese."

(e) (1) If cold-pack cheese is smoked, or made from cheeses which have been smoked, the word "smoked" shall precede or follow the name of the cold-pack cheese or the name of the cheese ingredient which was smoked.

(2) If it contains a substance prepared by condensing or precipitating wood smoke, the label shall bear the statement "with added ------------," the blank being filled in with the common or usual name of such ingredient.

(3) If it contains spice, the label shall bear the statement "spiced" or "spice added" or "with added spice," or in lieu of the word "spice" the common or usual name of the spice or spices used.

(4) If it contains added flavoring, the label shall bear the statement "flavoring added" or "with added flavoring" or "flavored with ------------," the blank being filled in with the common or usual name of the flavoring used; if the flavoring is artificial, the word "artificial" shall precede the word "flavoring" or the word "artificially" shall precede the statement "flavored with ------------."

(5) If it contains an added acidifying agent as prescribed in paragraph (c) (1) of this section, the label shall bear the statement "------------ added as a chemical preservative," the blank being filled in with the name or names of the acidifying agents used.

(f) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements herein specified, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 19.787 *Cold-pack cheese food; identity; label statement of optional ingredients.* (a) (1) Cold-pack cheese food is the food prepared by comminuting and mixing, without the aid of heat, one or more of the optional cheese ingredients prescribed in paragraph (c) of this section with one or more of the optional dairy ingredients prescribed in paragraph (d) of this section, into a homogeneous plastic mass. One or more of the optional ingredients specified in paragraph (e) of this section may be used.

(2) All cheeses used in a cold-pack cheese food are made from pasteurized milk, or are held for not less than 60 days at a temperature of not less than 35° F. before being comminuted.

(3) The moisture content of a cold-pack cheese food is not more than 44 percent, and the fat content is not less than 23 percent.

(4) Moisture and fat are determined by the methods prescribed in § 19.500 (c), except that in determining moisture the loss in weight which occurs in drying for 5 hours, under the conditions prescribed in such method, is taken as the weight of moisture.

(5) The weight of the cheese ingredient prescribed by subparagraph (1) of this paragraph constitutes not less than 51 percent of the weight of the finished cold-pack cheese food.

(6) The weight of each variety of cheese in the cold-pack cheese food made with two varieties of cheese is not less than 25 percent of the total weight of both, except that the weight of blue cheese, roquefort cheese, gorgonzola cheese, or limburger cheese is not less than 10 percent of the total weight of both. The weight of each variety of cheese in the cold-pack cheese food made with three or more varieties of cheese is not less than 15 percent of the total

weight of all, except that the weight of blue cheese, roquefort cheese, gorgonzola cheese, or limburger cheese is not less than 5 percent of the total weight of all. These limits do not apply to the quantity of cheddar cheese, washed curd cheese, colby cheese, and granular cheese in mixtures which are designated as "American cheese" as prescribed in paragraph (f) (6) of this section. Such mixtures are considered as one variety of cheese for the purposes of this subparagraph.

(b) Cold-pack cheese food may be smoked, or the cheese or cheeses from which it is made may be smoked, before comminuting and mixing, or it may contain substances prepared by condensing or precipitating wood smoke.

(c) The optional cheese ingredients referred to in paragraph (a) of this section are: One or more cheeses of the same or two or more varieties, except that cream cheese, neufchatel cheese, cottage cheese, creamed cottage cheese, cook cheese, and skim-milk cheese for manufacturing are not used, and except that semisoft part-skim cheese, part-skim spiced cheese, and hard grating cheese may not be used, alone or in combination with each other, as the cheese ingredient.

(d) The optional dairy ingredients referred to in paragraph (a) of this section are: cream, milk, skim milk, cheese whey, or any mixture of two or more of these or any of the foregoing from which part of the water has been removed, skim-milk cheese for manufacturing and albumin from cheese whey. All optional dairy ingredients used in cold-pack cheese food are pasteurized or made from products which have been pasteurized.

(e) The other optional ingredients referred to in paragraph (a) of this section are:

(1) An acidifying agent consisting of one or any mixture of two or more of the following: A vinegar, lactic acid, citric acid, acetic acid, and phosphoric acid, in such quantity that the pH of the finished cold-pack cheese food is not below 4.5.

(2) Water.

(3) Salt.

(4) Harmless artificial coloring.

(5) Spices or flavorings, other than any which singly or in combination with other ingredients simulate the flavor of cheese of any age or variety.

(6) A sweetening agent consisting of one or any mixture of two or more of the following: Sugar, dextrose, corn sugar, corn sirup, corn sirup solids, glucose sirup, glucose sirup solids, maltose, malt sirup, and hydrolyzed lactose, in a quantity necessary for seasoning.

(f) The label of a cold-pack cheese food shall bear the common or usual names of the optional ingredients used, as specified in paragraphs (c), (d), and (e) (1), (2), (3), and (6) of this section, and:

(1) If it is smoked, or made from cheeses which have been smoked, the word "smoked" shall precede or follow the name of the cold-pack cheese food or the name of the cheese ingredient which was smoked.

(2) If it contains a substance prepared by condensing or precipitating wood smoke, the label shall bear the statement "with added ____________," the blank being filled in with the common or usual name of such ingredient.

(3) If it contains spice, the label shall bear the statement "spiced," or "spice added," or "with added spice" or in lieu of the word "spice" the common or usual name of the spice used.

(4) If it contains added flavoring, the label shall bear the statement "flavoring added," "with added flavoring," or "flavored with ____________," the blank being filled in with the common or usual name of the flavoring used. If the flavoring is artificial, the word "artificial" shall precede the word "flavoring," or the word "artificially" shall precede the word "flavored," or the word "artificially" shall precede the statement "flavored with ______________________."

(5) If it contains added artificial coloring the label shall bear the statement "artificially colored" or "contains artificial color."

(6) If the cheese ingredient contains cheddar cheese, washed curd cheese, colby cheese, or granular cheese or any mixture of two or more of these, such cheese or such mixture may be designated as "American cheese."

(7) If an optional acidifying agent is used so that the pH of the finished food is less than 5.0, there shall appear after its name the words "a chemical preservative." In case vinegar is the only acidifying agent added it shall be considered to be acetic acid when the pH of the finished food is less than 5.0. In case vinegar and other acidifying agents are used and the pH of the finished food is less than 5.0, the name of the acidifying agents other than vinegar shall be followed by the statement "a chemical preservative."

(g) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements herein specified, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 19.788 *Cold-pack cheese food with fruits, vegetables, or meats; identity; label statement of optional ingredients.* (a) Cold-pack cheese food with fruits, vegetables, or meats or mixtures of these is the food which conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for cold-pack cheese food by § 19.787, except that:

(1) Its milk fat content is not less than 22 percent.

(2) It contains one or any mixture of two or more of the following: Any properly prepared fresh, cooked, canned, or dried vegetable; any properly prepared cooked or canned meat.

(3) When the added fruits, vegetables, or meats contain fat, the method prescribed for the determination of fat by § 19.500 (c) is not applicable.

(b) The name of a cold-pack cheese food with fruits, vegetables or meats is "Cold-pack cheese food with __________," the blank being filled in with the common or usual name or names of the fruits, vegetables, or meats used, in order of predominance by weight.

PART 25—DRESSINGS FOR FOODS

Sec.
25.1 Mayonnaise, mayonnaise dressing; identity; label statement of optional ingredients.
25.2 French dressing; identity; label statement of optional ingredients.
25.3 Salad dressing; identity; label statement of optional ingredients.

AUTHORITY: §§ 25.1 to 25.3 issued under sec. 701, 52 Stat. 1055; 21 U. S. C. 371. Interpret or apply sec. 401, 52 Stat. 1046, 68 Stat. 54; 21 U. S. C. 341.

§ 25.1 *Mayonnaise, mayonnaise dressing; identity; label statement of optional ingredients.* (a) Mayonnaise, mayonnaise dressing, is the emulsified semisolid food prepared from edible vegetable oil, one or both of the acidifying ingredients specified in paragraph (b) of this section, and one or more of the egg-yolk-containing ingredients specified in paragraph (c) of this section. It may be seasoned or flavored with one or more of the following ingredients:

(1) Salt.

(2) Sugar, dextrose, corn sirup, invert sugar sirup, nondiastatic maltose sirup, glucose sirup, honey. The foregoing sweetening ingredients may be used in sirup or dried form.

(3) Mustard, paprika, other spice, or any spice oil or spice extract, except that no turmeric or saffron is used and no spice oil or spice extract is used which imparts to the mayonnaise a color simulating the color imparted by egg yolk.

(4) Monosodium glutamate.

(5) Any suitable, harmless food seasoning or flavoring (other than imitations), provided it does not impart to the mayonnaise a color simulating the color imparted by egg yolk.

Mayonnaise may be mixed and packed in an atmosphere in which air is replaced in whole or in part by carbon dioxide or nitrogen. Mayonnaise contains not less than 65 percent by weight of vegetable oil.

(b) The acidifying ingredients referred to in paragraph (a) of this section are:

(1) Any vinegar or any vinegar diluted with water to an acidity, calculated as acetic acid, of not less than 2½ percent by weight, or any such vinegar or diluted vinegar mixed with the additional optional acidifying ingredient citric acid, but in any such mixture the weight of citric acid is not greater than 25 percent of the weight of the acids of the vinegar or diluted vinegar calculated as acetic acid. For the purpose of this paragraph, any blend of two or more vinegars is considered to be a vinegar.

(2) Lemon juice or lime juice or both or any such juice in frozen, canned, concentrated, or dried form, or any one or more of these diluted with water to an acidity, calculated as citric acid, of not less than 2½ percent by weight.

(c) The egg-yolk-containing ingredients referred to in paragraph (a) of this section are: Liquid egg yolks, frozen egg yolks, liquid whole eggs, frozen whole eggs, or any one or more of the foregoing with liquid egg white or frozen egg white.

(d) (1) When the additional optional acidifying ingredient as provided in paragraph (b) (1) of this section is used, the label shall bear the statement "Citric acid added" or "With added citric acid."

(2) Wherever the name "Mayonnaise" or "Mayonnaise Dressing" appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements specified in this paragraph, showing the optional ingredients present, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 25.2 *French dressing; identity; label statement of optional ingredients.* (a) French dressing is the separable liquid food or the emulsified viscous fluid food prepared from edible vegetable oil and one or both of the acidifying ingredients specified in paragraph (b) of this section. It may be seasoned or flavored with one or more of the following ingredients:

(1) Salt.

(2) Sugar, dextrose, corn sirup, invert sugar sirup, nondiastatic maltose sirup, glucose sirup, honey. The foregoing sweetening ingredients may be used in sirup or dried form.

(3) Mustard, paprika, other spice, or spice oil or spice extract.

(4) Monosodium glutamate.

(5) Any suitable, harmless food seasoning or flavoring (other than imitations).

(6) Tomato paste, tomato puree, catsup, sherry wine.

French dressing may be emulsified. Subject to the conditions hereinafter prescribed, one or both of the optional emulsifying ingredients specified in paragraph (c) (1) and (2) of this section may be added. French dressing may be mixed and packed in an atmosphere in which air is replaced in whole or in part by carbon dioxide or nitrogen. French dressing contains not less than 35 percent by weight of vegetable oil.

(b) The acidifying ingredients referred to in paragraph (a) of this section are:

(1) Any vinegar or any vinegar diluted with water, or any such vinegar or diluted vinegar mixed with the additional optional acidifying ingredient citric acid, but in any such mixture the weight of citric acid is not greater than 25 percent of the weight of the acids of the vinegar or diluted vinegar calculated as acetic acid. For the purpose of this paragraph, any blend of two or more vinegars is considered to be a vinegar.

(2) Lemon juice or lime juice or both or any such juice in frozen, canned, concentrated, or dried form, or any one or more of these diluted with water.

(c) The optional emulsifying ingredients referred to in paragraph (a) of this section are:

(1) Gum acacia (also called gum arabic), carob bean gum (also called locust bean gum), guar gum, gum karaya, gum tragacanth, extract of Irish moss, pectin, propylene glycol ester of alginic acid, sodium carboxymethylcellulose, or any mixture of two or more of these.

(2) Liquid egg yolks, frozen egg yolks, liquid whole eggs, frozen whole eggs, or any one or more of these with liquid egg white or frozen egg white. For the purpose of this paragraph, the quantity of egg-yolk-containing ingredient is calculated as the weight of the egg-yolk solids contained therein.

The quantity of any such emulsifying ingredient or mixture used amounts to not more than 0.75 percent by weight of the finished french dressing.

(d) (1) When the additional optional acidifying ingredient as provided in paragraph (b) (1) of this section is used, the label shall bear the statement "Citric acid added" or "With added citric acid." When an optional emulsifying ingredient as provided in paragraph (c) (1) of this section is used, the label shall bear the statement "__________ added" or "With added __________," the blank being filled in with the common name or names of the emulsifying ingredient or mixture of emulsifying ingredients used, as specified in paragraph (c) (1) of this section; or, alternatively, with the words "algin derivative," if propylene glycol ester of alginic acid is used; or with the words "vegetable gum" if any one of the vegetable gums, gum acacia, carob bean gum, guar gum, gum karaya, or gum tragacanth, is used; or with the words "vegetable gums" if two or more such vegetable gums are used. Label statements specified in this paragraph for declaring the presence of optional ingredients may be combined, as for example, "With added citric acid and sodium carboxymethylcellulose."

(2) Wherever the name "French Dressing" appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements specified in subparagraph (1) of this paragraph, showing the optional ingredients present, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 25.3 *Salad dressing; identity; label statement of optional ingredients.* (a) Salad dressing is the emulsified semisolid food prepared from edible vegetable oil, one or both of the acidifying ingredients specified in paragraph (b) of this section, one or more of the egg-yolk-containing ingredients specified in paragraph (c) of this section, and a cooked or partly cooked starchy paste prepared with a food starch, tapioca flour, wheat flour, rye flour, or any two or more of these. In the preparation of such starchy paste water may be added. Salad dressing may be seasoned or flavored with one or more of the following ingredients:

(1) Salt.

(2) Sugar, dextrose, corn sirup, invert sugar sirup, nondiastatic maltose sirup, glucose sirup, honey. The foregoing sweetening ingredients may be used in sirup or dried form.

(3) Mustard, paprika, other spice, or any spice oil or spice extract, except that no turmeric or saffron is used and no spice oil or spice extract is used which imparts to the salad dressing a color simulating the color imparted by egg yolk.

(4) Monosodium glutamate.

(5) Any suitable, harmless food seasoning or flavoring (other than imitations), provided it does not impart to the salad dressing a color simulating the color imparted by egg yolk.

Subject to the conditions hereinafter prescribed, one or more of the optional emulsifying ingredients specified in paragraph (d) of this section may be added. Salad dressing may be mixed and packed in an atmosphere in which air is replaced in whole or in part by carbon dioxide or nitrogen. Salad dressing contains not less than 30 percent by weight of vegetable oil and not less egg-yolk-containing ingredient than is equivalent in egg-yolk solids content to 4 percent by weight of liquid egg yolks.

(b) The acidifying ingredients referred to in paragraph (a) of this section are:

(1) Any vinegar or any vinegar diluted with water, or any such vinegar or diluted vinegar mixed with the additional optional acidifying ingredient citric acid, but in any such mixture the weight of citric acid is not greater than 25 percent of the weight of the acids of the vinegar or diluted vinegar calculated as acetic acid. For the purpose of this paragraph, any blend of two or more vinegars is considered to be a vinegar.

(2) Lemon juice or lime juice or both or any such juice in frozen, canned, concentrated, or dried form, or any one or more of these diluted with water.

(c) The egg-yolk-containing ingredients referred to in paragraph (a) of this section are: Liquid egg yolks, frozen egg yolks, liquid whole eggs, frozen whole eggs, or any one or more of the foregoing with liquid egg white or frozen egg white.

(d) The optional emulsifying ingredients referred to in paragraph (a) of this section are: Gum acacia (also called gum arabic), carob bean gum (also called locust bean gum), guar gum, gum karaya, gum tragacanth, extract of Irish moss, pectin, propylene glycol ester of alginic acid, sodium carboxymethylcellulose, or any mixture of two or more of these. The quantity used of any such emulsifying ingredient or mixture amounts to not more than 0.75 percent by weight of the finished salad dressing.

(e) (1) When the additional optional acidifying ingredient as provided in paragraph (b) (1) of this section is used, the label shall bear the statement "Citric acid added" or "With added citric acid." When an optional emulsifying ingredient as provided in paragraph (d) of this section is used, the label shall bear the statement "__________ added" or "With added __________," the blank being filled in with the common name or names of the emulsifying ingredient or mixture of emulsifying ingredients used, as specified in paragraph (d) of this section; or, alternatively, with the words "algin derivative," if propylene glycol ester of alginic acid is used; or with the words "vegetable gum" if any one of the vegetable gums, gum acacia, carob bean gum, guar gum, gum karaya, or gum tragacanth, is used; or with the words "vegetable gums," if two or more such vegetable gums are used. Label statements specified in this paragraph for declaring the presence of optional ingredients may be combined, as for example, "with added citric acid and sodium carboxymethylcellulose."

(2) Wherever the name "Salad Dressing" appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statements specified in this paragraph showing the optional ingredients present, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

PART 27—CANNED FRUITS; DEFINITIONS AND STANDARDS OF IDENTITY; QUALITY; AND FILL OF CONTAINER

Sec.	
27.0	Canned peaches; identity; label statement of optional ingredients.
27.1	Canned peaches; quality; label statement of substandard quality.
27.2	Canned peaches; fill of container; label statement of substandard fill.
27.3	Canned peaches with rum; identity; label statement of optional ingredients.
27.10	Canned apricots; identity; label statement of optional ingredients.
27.11	Canned apricots; quality; label statement of substandard quality.
27.12	Canned apricots; fill of container; label statement of substandard fill.
27.13	Canned apricots with rum; identity; label statement of optional ingredients.
27.20	Canned pears; identity; label statement of optional ingredients.
27.21	Canned pears; quality; label statement of substandard quality.
27.22	Canned pears; fill of container; label statement of substandard fill.
27.23	Canned pears with rum; identity; label statement of optional ingredients.
27.30	Canned cherries; identity; label statement of optional ingredients.
27.31	Canned cherries; quality; label statement of substandard quality.
27.32	Canned cherries; fill of containers; label statement of substandard fill.
27.33	Canned cherries with rum; identity; label statement of optional ingredients.
27.40	Canned fruit cocktail, canned cocktail fruits, canned fruits for cocktail; identity; label statement of optional ingredients.
27.41	Canned fruit cocktail, canned cocktail fruits, canned fruits for cocktail; quality; label statement of substandard quality.
27.42	Canned fruit cocktail, canned cocktail fruits, canned fruits for cocktail; fill of container; label statement of substandard fill.

AUTHORITY: §§ 27.0 to 27.42 issued under sec. 701 (a), 52 Stat. 1055; 21 U. S. C. 371 (a). Interpret or apply sec. 401, 52 Stat. 1046, 68 Stat. 54, 55; 21 U. S. C. 341.

§ 27.0 *Canned peaches; identity; label statement of optional ingredients.* (a) Canned peaches is the food prepared from one of the optional peach ingredients specified in paragraph (b) of this section and one of the optional packing media specified in paragraph (c) of this section. Such food may be seasoned with one or more of the following optional ingredients:

(1) Spice;

(2) Flavoring, other than artificial flavoring;

(3) A vinegar;

(4) Peach pits, except in the cases of peeled whole peaches and unpeeled whole peaches, in a quantity not more than 1 peach pit to each 8 ounces of finished canned peaches; and

(5) Peach kernels, except in the cases of peeled whole peaches and unpeeled whole peaches, and except when optional ingredient (4) is used.

Such food is sealed in a container and is so processed by heat as to prevent spoilage.

(b) The optional peach ingredients referred to in paragraph (a) of this section are prepared from mature peaches of the yellow clingstone, yellow freestone, white clingstone, or white freestone varietal group, and are in the following forms of units: peeled whole, unpeeled whole, peeled halves, unpeeled halves, peeled quarters, peeled slices, peeled dice, peeled mixed pieces of irregular sizes and shapes. Each such form of units prepared from each such varietal group is an optional peach ingredient. Each such ingredient, except in the case of peeled whole peaches and unpeeled whole peaches, is pitted. For the purpose of paragraph (e) of this section, the names of such optional peach ingredients are the words "Yellow Cling" or "Yellow Clingstone," "White Cling" or "White Clingstone," "Yellow Free" or "Yellow Freestone" or "White Free" or "White Freestone," as the case may be, preceded or followed by the word or words "Whole," "Unpeeled Whole," "Halves" or "Halved," "Unpeeled Halves," or "Unpeeled Halved," "Quarters" or "Quartered," "Slices" or "Sliced," "Dice" or "Diced," or "Mixed Pieces of Irregular Sizes and Shapes," as the case may be.

(c) (1) The optional packing media referred to in paragraph (a) of this section are:

(i) Water.
(ii) Peach juice.
(iii) Slightly sweetened water.
(iv) Light sirup.
(v) Heavy sirup.
(vi) Extra heavy sirup.
(vii) Slightly sweetened peach juice.
(viii) Light peach juice sirup.
(ix) Heavy peach juice sirup.
(x) Extra heavy peach juice sirup.

As used in this subparagraph the term "water" means, in addition to water, any mixture of water and peach juice; and the term "peach juice" means the fresh or canned expressed juice of mature peaches, of any varietal group specified in paragraph (b) of this section, to which no water is added, directly or indirectly.

(2) Each of packing media (1) (iii) to (x), inclusive, is prepared with a liquid ingredient and a saccharine ingredient. Water is the liquid ingredient from which packing media (1) (iii) to (vi), inclusive, are prepared, and peach juice is the liquid ingredient from which packing media (1) (vii) to (x), inclusive, are prepared. The saccharine ingredient from which packing media (1) (iii) to (x), inclusive, are prepared is one of the following: Sugar; any combination of sugar and dextrose in which the weight of the solids of the dextrose used is not more than one-half the weight of the solids of the sugar used; any combination of sugar and corn sirup or glucose sirup in which the weight of the solids of the corn sirup or glucose sirup used is not more than one-third the weight of the solids of the sugar used; or any combination of sugar, dextrose, and corn sirup or glucose sirup in which twice the weight of the solids of the dextrose used added to three times the weight of the solids of the corn sirup or glucose sirup used is not more than the weight of the solids of the sugar used; except that packing media (1) (vii) to (x), inclusive, are not prepared with any invert sugar sirup or with any corn sirup other than dried corn sirup or with any glucose sirup other than dried glucose sirup. A packing medium prepared with peach juice and any invert sugar sirup or corn sirup other than dried corn sirup or glucose sirup other than dried glucose sirup is considered to be prepared with water as the liquid ingredient.

(3) The respective densities of packing media (1) (iii) to (x), inclusive, as measured on the Brix hydrometer 15 days or more after the peaches are canned, are within the range prescribed for each in the following list:

Number of packing medium:	*Brix measurement*
(1) (iii) and (vii)	Less than 14°.
(1) (iv) and (viii)	14° or more but less than 19°.
(1) (v) and (ix)	19° or more but less than 24°.
(1) (vi) and (x)	24° or more but not more than 35°.

(d) For the purposes of this section:

(1) The term "sugar" means refined sucrose or invert sugar sirup. The term "invert sugar sirup" means an aqueous solution of inverted or partly inverted, refined or partly refined sucrose, the solids of which contain not more than 0.3 percent by weight of ash, and which is colorless, odorless, and flavorless, except for sweetness.

(2) The term "dextrose" means the hydrated or anhydrous, refined monosaccharide obtained from hydrolized starch.

(3) The term "corn sirup" means an aqueous solution obtained by the incomplete hydrolysis of cornstarch, and includes dried corn sirup; the solids of corn sirup and of dried corn sirup contain not less than 58 percent by weight of reducing sugars.

(4) The term "glucose sirup" means a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch. The solids of glucose sirup contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose. "Dried glucose sirup" means the product obtained by drying "glucose sirup."

(e) The label shall bear the name of the optional peach ingredient used, as specified in paragraph (b) of this section, and the name whereby the optional packing medium used is designated in paragraph (c) of this section, preceded by "In" or "Packed in." When any of the optional ingredients permitted by one of the following specified subparagraphs of paragraph (a) of this section is used, the label shall bear the words set forth below after the number of such subparagraph:

(1) "Spiced" or "Spice Added" or "With Added Spice," or in lieu of the word "Spice," the common name of the spice;

(2) "Flavoring Added" or "With Added Flavoring," or, in lieu of the word "Flavoring," the common name of the flavoring;

(3) "Seasoned with Vinegar" or "Seasoned with ____________ Vinegar," the blank being filled in with the word showing the kind of vinegar used;

(4) "Seasoned with Peach Pits";

(5) "Seasoned with Peach Kernels."

When two or more of the optional ingredients specified in paragraph (a) (1) (2), (3), and (4) or (5) of this section are used, such words may be combined, as for example, "Seasoned with Cider Vinegar, Cloves, Cinnamon Oil, and Peach Kernels."

(f) Wherever the name "peaches" appears on the label so conspicuously as to be easily seen under the customary conditions of purchase, the words specified in this section, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name without intervening written, printed, or graphic matter, except that the specific varietal name of the peaches may so intervene.

§ 27.1 *Canned peaches; quality; label statement of substandard quality.* (a) The standard of quality for canned peaches is as follows:

(1) All units tested in accordance with the method prescribed in paragraph (b) of this section are pierced by a weight of not more than 300 grams;

(2) In the cases of halves and quarters, the weight of each unit is not less than ⅗ ounce and 3/10 ounce, respectively;

(3) In the cases of whole peaches, halves, and quarters, the weight of the largest unit in the container is not more than twice the weight of the smallest unit therein;

(4) Except in the case of unpeeled peaches, there is present in the finished canned peaches not more than 1 square inch of peel per each 1 pound of net contents;

(5) Not more than 20 percent of the units in the container are blemished with scab, hail injury, discoloration, or other abnormalities;

(6) In the cases of whole peaches, halves, quarters, and slices, all units are untrimmed, or are so trimmed as to preserve normal shape; and

(7) Except in the case of mixed pieces of irregular sizes and shapes, not more than 5 percent of the units in a container of 20 or more units, and not more than one unit in a container of less than 20 units, is crushed or broken. (A unit which has lost its normal shape because of ripeness and which bears no mark of crushing shall not be considered to be crushed or broken.)

(b) Canned peaches shall be tested by the following method to determine whether or not they meet the requirements of paragraph (a) (1) of this section: So trim a test piece from the unit as to fit, with peel surface up, into a supporting receptacle. If the unit is of different firmness in different parts of its peel surface, trim the piece from the firmest part. If the piece is unpeeled, remove the peel. The top of the receptacle is circular in shape, of 1⅛ inches inside diameter, with vertical sides; or rectangular in shape, ¾ inch by 1 inch inside measurements, with ends vertical and sides sloping downward and joining at the center at a vertical depth of ¾ inch. Use the circular receptacle for testing units of such size that a test piece can be trimmed therefrom to fit it. Use the rectangular receptacle for testing other units. Test no unit from which a test piece with rectangular peel surface at least ½ inch by 1 inch cannot be trimmed. Test the piece by means of a round metal rod 5/32 inch in diameter. To the upper end of the rod is affixed a device to which weight can be added. The rod is held vertically by a support through which it can freely move upward or downward. The lower end of the rod is a plane surface to which the vertical axis of the rod is perpendicular. Adjust the combined weight of the rod and device to 100 grams. Set the receptacle so that the surface of the test piece is held horizontally. Lower the end of the rod to the approximate center of such surface, and add weight to the device at a uniform, continuous rate of 12 grams per second until the rod pierces the test piece. Weigh the rod and weighted device. Test all units in containers of 50 units or less, except those units too small for testing or too soft for trimming. Test at least 50 units, taken at random, in containers of more than 50 units; but if less than 50 units are of sufficient size and firmness for testing, test those which are of sufficient size and firmness.

(c) If the quality of canned peaches falls below the standard prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard quality specified in § 10.2 (a) of this chapter, in the manner and form therein specified; but in lieu of such general statement of substandard quality, the label may bear the alternative statement "Below Standard in Quality_____," the blank to be filled in with the words specified after the corresponding number of each clause of paragraph (a) of this section which such canned peaches fail to meet, as follows: (1) "Not Tender"; (2) "Small Halves," or "Small Quarters," as the case may be; (3) "Mixed Sizes"; (4) "Not Well Peeled"; (5) "Blemished"; (6) "Unevenly Trimmed"; (7) "Partly Crushed or Broken." Such alternative statement shall immediately and conspicuously precede or follow, without intervening written, printed, or graphic matter, the name "Peaches" and any words and statements required or authorized to appear with such name by § 27.0 (b).

§ 27.2 *Canned peaches; fill of container; label statement of substandard fill.* (a) The standard of fill of container for canned peaches is the maximum quantity of the optional peach ingredient which can be sealed in the container and processed by heat to prevent spoilage, without crushing or breaking such ingredient.

(b) If canned peaches fall below the standard of fill of container prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard fill specified in § 10.2 (b) of this chapter, in the manner and form therein specified.

§ 27.3 *Canned peaches with rum; identity; label statement of optional ingredients.* Canned peaches with rum conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for canned peaches by § 27.0, except that it contains added rum in such amount that its alcohol content is more than 3 percent but less than 5 percent by weight.

§ 27.10 *Canned apricots; identity; label statement of optional ingredients.* (a) Canned apricots is the food prepared from one of the optional apricot ingredients specified in paragraph (b) of this section and one of the optional packing media specified in paragraph (c) of this section. Such food may be seasoned with one or more of the following optional ingredients:

(1) Spice;

(2) Flavoring, other than artificial flavoring;

(3) A vinegar;

(4) Apricot pits, except in the cases of unpeeled whole apricots and peeled whole apricots, in a quantity not more than 1 apricot pit to each 8 ounces of finished canned apricots;

(5) Apricot kernels, except in the cases of unpeeled whole apricots and peeled whole apricots, and except when optional ingredient (4) is used.

Such food is sealed in a container and so processed by heat as to prevent spoilage.

(b) The optional apricot ingredients referred to in paragraph (a) of this section are prepared from mature apricots and are in the following forms of units: unpeeled whole, peeled whole, unpeeled halves, peeled halves, unpeeled quarters, peeled quarters, unpeeled slices, peeled slices, unpeeled mixed pieces of irregular sizes and shapes, peeled mixed pieces of irregular sizes and shapes. Each such form of units is an optional apricot ingredient. Each such ingredient, except in the cases of unpeeled whole apricots and peeled whole apricots, is pitted. For the purposes of paragraph (e) of this section, the names of such optional apricot ingredients are "Whole," "Halves," or "Halved," "Quarters" or "Quartered," "Slices" or "Sliced," "Mixed Pieces of Irregular Sizes and Shapes," as the case may be, preceded or followed by "Unpeeled" or "Peeled," as the case may be.

(c) (1) The optional packing media referred to in paragraph (a) of this section are:

(i) Water.

(ii) Apricot juice.

(iii) Slightly sweetened water.

(iv) Light sirup.

(v) Heavy sirup.

(vi) Extra heavy sirup.

(vii) Slightly sweetened apricot juice.
(viii) Light apricot juice sirup.
(ix) Heavy apricot juice sirup.
(x) Extra heavy apricot juice sirup.

As used in this subparagraph the term "water" means, in addition to water, any mixture of water and apricot juice; and the term "apricot juice" means the fresh or canned expressed juice of mature apricots to which no water is added, directly or indirectly.

(2) Each of packing media (1) (iii) to (x), inclusive, is prepared with a liquid ingredient and a saccharine ingredient. Water is the liquid ingredient from which packing media (1) (iii) to (vi), inclusive, are prepared, and apricot juice is the liquid ingredient from which packing media (1) (vii) to (x), inclusive, are prepared. The saccharine ingredient from which packing media (1) (iii) to (x), inclusive, are prepared is one of the following: Sugar; any combination of sugar and dextrose in which the weight of the solids of the dextrose used is not more than one-half the weight of the solids of the sugar used; any combination of sugar and corn sirup or glucose sirup in which the weight of the solids of the corn sirup or glucose sirup used is not more than one-third the weight of the solids of the sugar used; or any combination of sugar, dextrose, and corn sirup or glucose sirup in which twice the weight of the solids of the dextrose used added to three times the weight of the solids of the corn sirup or glucose sirup used is not more than the weight of the solids of the sugar used; except that packing media (1) (vii) to (x), inclusive, are not prepared with any invert sugar sirup or with any corn sirup other than dried corn sirup or with any glucose sirup other than dried glucose sirup. A packing medium prepared with apricot juice and any invert sugar sirup or corn sirup other than dried corn sirup or glucose sirup other than dried glucose sirup is considered to be prepared with water as the liquid ingredient.

(3) The respective densities of packing media (1) (iii) to (x), inclusive, as measured on the Brix hydrometer 15 days or more after the apricots are canned, are within the range prescribed for each in the following list:

Number of packing medium:	*Brix measurement*
(1) (iii) and (vii)	Less than 16°.
(1) (iv) and (viii)	16° or more but less than 21°.
(1) (v) and (ix)	21° or more but less than 25°.
(1) (vi) and (x)	25° or more but not more than 40°.

(d) For the purposes of this section:

(1) The term "sugar" means refined sucrose or invert sugar sirup. The term "invert sugar sirup" means an aqueous solution of inverted or partly inverted, refined or partly refined sucrose, the solids of which contain not more than 0.3 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

(2) The term "dextrose" means the hydrated or anhydrous, refined monosaccharide obtained from hydrolized starch.

(3) The term "corn sirup" means an aqueous solution obtained by the incomplete hydrolysis of cornstarch, and includes dried corn sirup; the solids of corn sirup and of dried corn sirup contain not less than 58 percent by weight of reducing sugars.

(4) The term "glucose sirup" means a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch. The solids of glucose sirup contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose. "Dried glucose sirup" means the product obtained by drying "glucose sirup."

(e) The label shall bear the name of the optional apricot ingredient used, as specified in paragraph (b) of this section, and the name whereby the optional packing medium used is designated in paragraph (c) of this section, preceded by "In" or "Packed in." When any optional ingredient permitted by one of the following specified subparagraphs of paragraph (a) is used, the labels shall bear the words set forth below after the number of such subparagraph:

(1) "Spiced" or "Spice Added" or "With Added Spice," or, in lieu of the word "Spice," the common name of the spice;

(2) "Flavoring Added" or "With Added Flavoring," or, in lieu of the word "Flavoring," the common name of the flavoring;

(3) "Seasoned with Vinegar" or "Seasoned with ______________ Vinegar," the blank being filled in with the word showing the kind of vinegar used;

(4) "Seasoned with Apricot Pits";

(5) "Seasoned with Apricot Kernels."

When two or more of the optional ingredients specified in paragraph (a) (1), (2), (3), and (4) or (5) of this section are used, such words may be combined, as for example, "Seasoned with Cider Vinegar, Cloves, Cinnamon Oil, and Apricot Kernels."

(f) Wherever the name "apricots" appears on the label so conspicuously as to be easily seen under the customary conditions of purchase, the words specified in this section, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name without intervening written, printed, or graphic matter, except that the specific varietal name of the apricots may so intervene.

§ 27.11 *Canned apricots; quality; label statement of substandard quality.* (a) The standard of quality for canned apricots is as follows:

(1) All units tested in accordance with the method prescribed in paragraph (b) of this section are pierced by a weight of not more than 300 grams;

(2) In the cases of halves and quarters, the weight of each unit is not less than ⅖ ounce and ⅓ ounce, respectively;

(3) In the cases of whole apricots, halves, and quarters, the weight of the largest unit in the container is not more than twice the weight of the smallest unit therein;

(4) Not more than 20 percent of the units in the container are blemished with scab, hail injury, discoloration, or other abnormalities;

(5) In the cases of whole apricots, halves, and quarters, all units are untrimmed, or are so trimmed as to preserve normal shape; and

(6) Except in the case of mixed pieces of irregular sizes and shapes, not more than 5 percent of the units in a container of 20 or more units, and not more than 1 unit in a container of less than 20 units, is crushed or broken. (A unit which has lost its normal shape because of ripeness and which bears no mark of crushing shall not be considered to be crushed or broken.)

(b) Canned apricots shall be tested by the following method to determine whether or not they meet the requirements of paragraph (a) (1) of this section: So trim a test piece from the unit as to fit, with peel surface up, into a supporting receptacle. If the unit is of different firmness in different parts of its peel surface, trim the piece from the firmest part. If the piece is unpeeled, remove the peel. The top of the receptacle is circular in shape, of 1⅛ inches inside diameter, with vertical sides; or rectangular in shape, ¾ inch by 1 inch inside measurements, with ends vertical and sides sloping downward and joining at the center at a vertical depth of ¾ inch. Use the circular receptacle for testing units of such size that a test piece can be trimmed therefrom to fit it. Use the rectangular receptacle for testing other units. Test no unit from which a test piece with rectangular peel surface at least ½ inch by 1 inch cannot be trimmed. Test the piece by means of a round metal rod $\frac{3}{16}$ inch in diameter. To the upper end of the rod is affixed a device to which weight can be added. The rod is held vertically by a support through which it can freely move upward or downward. The lower end of the rod is a plane surface to which the vertical axis of the rod is perpendicular. Adjust the combined weight of the rod and device to 100 grams. Set the receptacle so that the surface of the test piece is held horizontally. Lower the end of the rod to the approximate center of such surface, and add weight to the device at a uniform, continuous rate of 12 grams per second until the rod pierces the test piece. Weigh the rod and weighted device. Test all units in containers of 50 units or less, except those units too small for testing or too soft for trimming. Test at least 50 units, taken at random, in containers of more than 50 units; but if less than 50 units are of sufficient size and firmness for testing, test those which are of sufficient size and firmness.

(c) If the quality of canned apricots falls below the standard prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard quality specified in § 10.2 (a) of this chapter, in the manner and form therein specified; but in lieu of such general statement of substandard quality, the label may bear the alternative statement "Below Standard in Quality_____," the blank to be filled in with the words specified after the corresponding number of each subparagraph of paragraph (a) of this section which such canned apricots fail to meet, as follows: (1) "Not Tender"; (2) "Small Halves," or "Small Quarters," as the case may be: (3) "Mixed Sizes"; (4) "Blemished"; (5) "Unevenly Trimmed"; (6) "Partly Crushed or Broken." Such alternative statement shall immediately and conspicuously precede or follow, without intervening written, printed, or graphic matter, the name "Apricots" and any words and statements required or authorized to appear with such name by § 27.10 (b).

§ 27.12 *Canned apricots; fill of container; label statement of substandard fill.* (a) The standard of fill of container for canned apricots is the maximum quantity of the optional apricot ingredient which can be sealed in the container and processed by heat to prevent spoilage, without crushing or breaking such ingredient.

(b) If canned apricots fall below the standard of fill of container prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard fill specified in § 10.2 (b) of this chapter, in the manner and form therein specified.

§ 27.13 *Canned apricots with rum; identity; label statement of optional ingredients.* Canned apricots with rum conforms to the definition and standard of identity and is subject to the requirements for label statement of optional ingredients, prescribed for canned apricots by § 27.10, except that it contains added rum in such amount that its alcohol content is more than 3 percent but less than 5 percent by weight.

§ 27.20 *Canned pears; identity; label statement of optional ingredients.* (a) Canned pears is the food prepared from one of the optional pear ingredients specified in paragraph (b) of this section and one of the optional packing media specified in paragraph (c) of this section. Such food may be seasoned with one or more of the following optional ingredients:

(1) Spice;
(2) Flavoring, other than artificial flavoring; and
(3) A vinegar.

Such food is sealed in a container and so processed by heat as to prevent spoilage.

(b) The optional pear ingredients referred to in paragraph (a) of this section are prepared from mature pears and are in the following forms of units: peeled whole, unpeeled whole, peeled halves, unpeeled halves, peeled quarters, peeled slices, peeled dice, peeled mixed pieces of irregular sizes and shapes. Each such form of units is an optional pear ingredient. Each such ingredient, except in the cases of peeled whole pears and unpeeled whole pears, is cored. For the purposes of paragraph (e) of this section, the respective names of such optional pear ingredients are "Whole," "Halves" or "Halved," "Quarters" or "Quartered," "Slices" or "Sliced," "Dice" or "Diced," "Mixed Pieces of Irregular Sizes and Shapes," preceded or followed in case the units are whole or halves and are unpeeled, by the word "Unpeeled."

(c) (1) The optional packing media referred to in paragraph (a) of this section are:

(i) Water.
(ii) Pear juice.
(iii) Slightly sweetened water.
(iv) Light sirup.
(v) Heavy sirup.
(vi) Extra heavy sirup.
(vii) Slightly sweetened pear juice.
(viii) Light pear juice sirup.
(ix) Heavy pear juice sirup.
(x) Extra heavy pear juice sirup.

As used in this subparagraph the term "water" means, in addition to water, any mixture of water and pear juice; and the term "pear juice" means the fresh or canned expressed juice of mature pears to which no water is added, directly or indirectly.

(2) Each of packing media (1) (iii) to (x), inclusive, is prepared with a liquid ingredient and a saccharine ingredient. Water is the liquid ingredient from which packing media (1) (iii) to (vi), inclusive, are prepared, and pear juice is the liquid ingredient from which packing media (1) (vii) to (x), inclusive, are prepared. The saccharine ingredient from which packing media (1) (iii) to (x), inclusive, are prepared is one of the following: Sugar; any combination of sugar and dextrose in which the weight of the solids of the dextrose used is not more than one-half the weight of the solids of the sugar used; any combination of sugar and corn sirup or glucose sirup in which the weight of the solids of the corn sirup or glucose sirup used is not more than one-third the weight of the solids of the sugar used; or any combination of sugar, dextrose, and corn sirup or glucose sirup in which twice the weight of the solids of the dextrose used added to three times the weight of the solids of the corn sirup or glucose sirup used is not more than the weight of the solids of the sugar used; except that packing media (1) (vii) to (x), inclusive, are not prepared with any invert sugar sirup or with any corn sirup other than dried corn sirup or with any glucose sirup other than dried glucose sirup. A packing medium prepared with pear juice and any invert sugar sirup or corn sirup other than dried corn sirup or glucose sirup other than dried glucose sirup is considered to be prepared with water as the liquid ingredient.

(3) The respective densities of packing media (1) (iii) to (x), inclusive, as measured on the Brix hydrometer 15 days or more after the pears are canned, are within the range prescribed for each in the following list:

Number of packing medium:	*Brix measurement*
(1) (iii) and (vii)	Less than 14°.
(1) (iv) and (viii)	14° or more but less than 18°.
(1) (v) and (ix)	18° or more but less than 22°.
(1) (vi) and (x)	22° or more but not more than 35°.

(d) For the purposes of this section:

(1) The term "sugar" means refined sucrose or invert sugar sirup. The term "invert sugar sirup" means an aqueous solution of inverted or partly inverted, refined or partly refined sucrose the solids of which contain not more than 0.3 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

(2) The term "dextrose" means the hydrated or anhydrous, refined monosaccharide obtained from hydrolized starch.

(3) The term "corn sirup" means an aqueous solution obtained by the incomplete hydrolysis of cornstarch, and includes dried corn sirup; the solids of corn sirup and of dried corn sirup contain not less than 58 percent by weight of reducing sugars.

(4) The term "glucose sirup" means a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch. The solids of glucose sirup contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose. "Dried glucose sirup" means the product obtained by drying "glucose sirup."

(e) The label shall bear the name of the optional pear ingredient used, as specified in paragraph (b) of this section, and the name whereby the optional packing medium used is designated in paragraph (c) of this section, preceded by "In" or "Packed in." When any optional ingredient permitted by one of the following specified subparagraphs of paragraph (a) of this section is used, the label shall bear the words set forth below after the number of such subparagraph:

(1) "Spiced" or "Spice Added" or "With Added Spice," or, in lieu of the word "Spice," the common name of the spice;

(2) "Flavoring Added" or "With Added Flavoring," or, in lieu of the word "Flavoring," the common name of the flavoring;

(3) "Seasoned with Vinegar" or "Seasoned with ________ Vinegar," the blank being filled in with the word showing the kind of vinegar used.

When two or all of the optional ingredients specified in paragraph (a) (1), (2), and (3) of this section are used, such words may be combined, as for example, "Seasoned with Cider Vinegar, Cloves, and Cinnamon Oil."

(f) Wherever the name "pears" appears on the label so conspicuously as to be easily seen under the customary conditions of purchase, the words specified in this section, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name without intervening written, printed, or graphic matter, except that the specific varietal name of the pears may so intervene.

§ 27.21 *Canned pears; quality; label statement of substandard quality.* (a) The standard of quality for canned pears is as follows:

(1) All units tested in accordance with the method prescribed in paragraph (b) of this section are pierced by a weight of not more than 300 grams;

(2) In the cases of halves and quarters, the weight of each unit is not less than ⅗ ounce and 3/10 ounce, respectively;

(3) In the cases of whole pears, halves, and quarters, the weight of the largest unit in the container is not more than twice the weight of the smallest unit therein;

(4) Except in the case of unpeeled pears, there is present in the finished canned pears not more than 1 square inch of peel per each 1 pound of net contents;

(5) Not more than 20 percent of the units in the container are blemished with scab, hail injury, discoloration, or other abnormalities;

(6) In the cases of whole pears, halves, and quarters, all units are untrimmed, or are so trimmed as to preserve normal shape; and

(7) Except in the case of mixed pieces of irregular sizes and shapes, not more than 10 percent of the units in a container of 10 or more units, and not more than 1 unit in a container of less than 10 units, is crushed or broken. (A unit which has lost its normal shape because of ripeness and which bears no mark of crushing shall not be considered to be crushed or broken.)

(b) Canned pears shall be tested by the following method to determine whether or not they meet the requirements of paragraph (a) (1) of this section: So trim a test piece from the unit as to fit, with peel surface up, into a supporting receptacle. If the unit is of different firmness in different parts of its peel surface, trim the piece from the firmest part. If the piece is unpeeled remove the peel. The top of the receptacle is circular in shape of 1⅛ inches inside diameter, with vertical sides; or rectangular in shape, ¾ inch by 1 inch inside measurements, with ends vertical and sides sloping downward and joining at the center at a vertical depth of ¾ inch. Use the circular receptacle for testing units of such size that a test piece can be trimmed therefrom to fit it. Use the rectangular receptacle for testing other units. Test no unit from which a test piece with rectangular peel surface at least ½ inch by 1 inch cannot be trimmed. Test the piece by means of a round metal rod 5/32 inch in diameter. To the upper end of the rod is affixed a device to which weight can be added. The rod is held vertically by a support through which it can freely move upward or downward. The lower end of the rod is a plane surface to which the vertical axis of the rod is perpendicular. Adjust the combined weight of the rod and device to 100 grams. Set the receptacle so that the surface of the test piece is held horizontally. Lower the end of the rod to the approximate center of such surface, and add weight to the device at a uniform, continuous rate of 12 grams per second until the rod pierces the test piece. Weigh the rod and weighted device. Test all units in containers of 50 units or less, except those units too small for testing or too soft for trimming. Test at least 50 units, taken at random, in containers of more than 50 units; but if less than 50 units are of sufficient size and firmness for testing, test those which are of sufficient size and firmness.

(c) If the quality of canned pears falls below the standard prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard quality specified in § 10.2 (a) of this chapter in the manner and form therein specified; but in lieu of such general statement of substandard quality, the label may bear the alternative statement "Below Standard in Quality ____," the blank to be filled in with the words specified after the corresponding number of each subparagraph of paragraph (a) of this section which such canned pears fail to meet, as follows: (1) "Not Tender"; (2) "Small Halves" or "Small Quarters," as the case may be; (3) "Mixed Sizes"; (4) "Not Well Peeled"; (5) "Blemished"; (6) "Unevenly Trimmed"; (7) "Partly Crushed or Broken." Such alternative statement shall immediately and conspicuously precede or follow, without intervening written, printed, or graphic matter, the name "Pears" and any words and statements required or authorized to appear with such names by § 27.20 (b).

§ 27.22 *Canned pears; fill of container; label statement of substandard fill.* (a) The standard of fill of container for canned pears is the maximum quantity of the optional pear ingredient which can be sealed in the container and processed by heat to prevent spoilage, without crushing or breaking such ingredient.

(b) If canned pears fall below the standard of fill of container prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard fill specified in § 10.2 (b) of this chapter, in the manner and form therein specified.

§ 27.23 *Canned pears with rum; identity; label statement of optional ingredients.* Canned pears with rum conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for canned pears by § 27.20, except that it contains added rum in such amount that its alcohol content is more than 3 percent but less than 5 percent by weight.

§ 27.30 *Canned cherries; identity; label statement of optional ingredients.* (a) Canned cherries is the food prepared from one of the optional cherry ingredients specified in paragraph (b) of this section and one of the optional packing media specified in paragraph (c) of this section. Such food may be seasoned with one or more of the following optional ingredients:

(1) Spice;

(2) Flavoring, other than artificial flavoring;

(3) A vinegar.

Such food is sealed in a container and so processed by heat as to prevent spoilage.

(b) The optional cherry ingredients referred to in paragraph (a) of this section are prepared from mature cherries of the red sour, light sweet, or dark sweet varietal group. Pitted cherries of each such group and unpitted cherries of each such group are an optional cherry ingredient. For the purposes of paragraph (e) of this section, the names of such optional cherry ingredients are the words "Red Sour" or "Red Tart," "Light Sweet" or "Dark Sweet," as the case may be, preceded or followed by the word "Pitted" in case such ingredients are pitted.

(c) (1) The optional packing media referred to in paragraph (a) of this section are:

(i) Water.
(ii) Cherry juice.
(iii) Slightly sweetened water.
(iv) Light sirup.
(v) Heavy sirup.
(vi) Extra heavy sirup.
(vii) Slightly sweetened cherry juice.
(viii) Light cherry juice sirup.
(ix) Heavy cherry juice sirup.
(x) Extra heavy cherry juice sirup.

As used in this subparagraph the term "water" means, in addition to water, any mixture of water and cherry juice; and the term "cherry juice" means the fresh or canned expressed juice of mature cherries, of any varietal group specified in paragraph (b) of this section, to which no water is added directly, or indirectly.

(2) Each of packing media (1) (iii) to (x), inclusive, is prepared with a liquid ingredient and a saccharine ingredient. Water is the liquid ingredient from which packing media (1) (iii) to (vi), inclusive, are prepared, and cherry juice is the liquid ingredient from which packing media (1) (vii) to (x), inclusive, are prepared. The saccharine ingredient from which packing media (1) (iii) to (x), inclusive, are prepared is one of the following: Sugar; any combination of sugar and dextrose in which the weight of the solids of the dextrose used is not more than one-half the weight of the solids of the sugar used; any combination of sugar and corn sirup or glucose sirup in which the weight of the solids of the corn sirup or glucose sirup used is not more than one-third the weight of the solids of the sugar used; or any combination of sugar, dextrose, and corn sirup or glucose sirup in which twice the weight of the solids of the dextrose used added to three times the weight of the solids of the corn sirup or glucose sirup used is not more than the weight of the solids of the sugar used; except that packing media (1) (vii) to (x), inclusive, are not prepared with any invert sugar sirup or with any corn sirup other than dried corn sirup or with any glucose sirup other than dried glucose sirup. A packing medium prepared with cherry juice and any invert sugar sirup or corn sirup other than dried corn sirup or glucose sirup other than dried glucose sirup is considered to be prepared with water as the liquid ingredient.

(3) The respective densities of packing media (1) (iii) to (x), inclusive, as measured on the Brix hydrometer 15 days or more after the cherries are canned, are within the range prescribed for each in the following list:

Number of packing medium:	Brix measurement
In case of sweet cherries:	
(1) (iii) and (vii)	Less than 16°.
(1) (iv) and (viii)	16° or more but less than 20°.
(1) (v) and (ix)	20° or more but less than 25°.
(1) (vi) and (x)	25° or more but not more than 35°.
In case of red sour cherries:	
(1) (iii) and (vii)	Less than 18°.
(1) (iv) and (viii)	18° or more but less than 22°.
(1) (v) and (ix)	22° or more but less than 28°.
(1) (vi) and (x)	28° or more but not more than 45°.

(d) For the purposes of this section:

(1) The term "sugar" means refined sucrose or invert sugar sirup. The term "invert sugar sirup" means an aqueous solution of inverted or partly inverted, refined or partly refined sucrose, the solids of which contain not more than 0.3 percent by weight of ash, and which is colorless, odorless, and flavorless except for sweetness.

(2) The term "dextrose" means the hydrated or anhydrous, refined monosaccharide obtained from hydrolized starch.

(3) The term "corn sirup" means an aqueous solution obtained by the incomplete hydrolysis of cornstarch, and includes dried corn sirup; the solids of corn sirup and of dried corn sirup contain not less than 58 percent by weight of reducing sugars.

(4) The term "glucose sirup" means a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch. The solids of glucose sirup contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose. "Dried glucose sirup" means the product obtained by drying "glucose sirup."

(e) The label shall bear the name of the optional cherry ingredient used, as specified in paragraph (b) of this section, and the name whereby the optional packing medium used is designated in paragraph (c) of this section, preceded by "In" or "Packed in." When any optional ingredient permitted by one of the following specified subparagraphs of paragraph (a) of this section is used, the label shall bear the words set forth below after the number of such subparagraph:

(1) "Spiced" or "Spice Added" or "With Added Spice," or, in lieu of the word "Spice," the common name of the spice;

(2) "Flavoring Added" or "With Added Flavoring," or, in lieu of the word "Flavoring," the common name of the flavoring;

(3) "Seasoned with Vinegar" or "Seasoned with ____________ Vinegar," the blank being filled in with the word showing the kind of vinegar used.

When two or all of the optional in ingredients specified in paragraph (a) (1), (2), and (3) of this section are used, such words may be combined, as for example, "Seasoned with Cider Vinegar, Cloves, and Cinnamon Oil."

(f) Wherever the name "cherries" appears on the label so conspicuously as to be easily seen under the customary conditions of purchase, the words specified in this section showing the optional ingredients used, shall immediately and conspicuously precede or follow such name without intervening written, printed, or graphic matter except that the specific varietal name of the cherries may so intervene.

§ 27.31 *Canned cherries; quality; label statement of substandard quality.* (a) The standard of quality for canned cherries is as follows:

(1) In the case of pitted cherries, not more than 1 pit is present in each 20 ounces of canned cherries, as determined by the method prescribed in paragraph (b) (1) of this section;

(2) In the case of unpitted cherries, the weight of each cherry in the container is not less than $\frac{1}{10}$ ounce;

(3) In the case of unpitted cherries, the weight of the largest cherry in the container is not more than twice the weight of the smallest cherry therein;

(4) In the case of unpitted cherries, the total weight of pits is not more than 12 percent of the weight of drained cherries, as determined by the method prescribed in paragraph (b) (2) of this section; and

(5) Not more than 15 percent by count of the cherries in the container are blemished with scab, hail injury, discoloration, scar tissue, or other abnormality. A unit showing skin discloration having an aggregate area not exceeding that of a circle $\frac{3}{16}$ inch in diameter and not extending into the fruit tissue shall not be considered as blemished.

(b) (1) Pitted canned cherries shall be tested by the following method to determine whether or not they comply with the requirements of paragraph (a) (1) of this section: Take at random such number of containers as to have a total quantity of contents of at least 24 pounds. Open the containers and weigh the contents. Count the pits and pieces of pit shell in such total quantity. Count a piece of pit shell equal to or smaller than one-half pit shell as one-half pit, and a piece of pit shell larger than one-half pit shell as one pit; but when two or more pieces of pit shell are within or attached to a single cherry, count such pieces as one-half pit if their combined size is equivalent to that of one-half pit shell or less, and as one pit if their combined size is equivalent to that of more than one-half pit shell. From the total number of pits so counted and the combined weight of the contents of all the containers, calculate the number of pits present in each 20 ounces of canned cherries.

(2) Unpitted canned cherries shall be tested by the following method to determine whether or not they comply with the requirements of paragraph (a) (4) of this section: Tilt the opened container so as to distribute the contents over the meshes of a circular sieve which has previously been weighed. The diameter of the sieve is 8 inches if the quantity of the contents of the container is less than 3 pounds, or 12 inches if such quantity is 3 pounds or more. The bottom of the sieve is No. 8 woven-wire cloth which complies with the specifications for such cloth set forth on page 3 of "Standard Specifications for Sieves," published October 25, 1938, by United States Department of Commerce, National Bureau of Standards. Without shifting the cherries, so incline the sieve as to facilitate drainage. Two minutes from the time drainage begins, weight the sieve and drained cherries. The weight so found, less the weight of the sieve, shall be considered to be the weight of drained cherries. Pit the cherries and wash the pits free from adhering flesh. Drain and weigh the pits by the method prescribed above. Divide the weight of pits so found by the weight of drained cherries, and multiply by 100.

(c) If the quality of canned cherries falls below the standard prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard quality specified in § 10.2 (a) of this chapter, in the manner and form therein specified; but in lieu of such general statement of substandard quality, the label may bear the alternative statement "Below Standard in Quality ______," the blank to be filled in with the words specified after the corresponding number of each subparagraph of paragraph (a) of this section which such canned cherries fail to meet, as follows: (1) "Partially Pitted"; (2) "Small"; (3) "Mixed Sizes"; (4) "Thin Fleshed"; (5) "Blemished." Such alternative statement shall immediately and conspicuously precede or follow, without intervening written, printed, or graphic matter, the name "Cherries" and any words and statements required or authorized to appear with such name by § 27.30 (b).

§ 27.32 *Canned cherries; fill of container; label statement of substandard fill.* (a) The standard of fill of container for canned cherries is the maximum quantity of the optional cherry ingredient which can be sealed in the container and processed by heat to prevent spoilage, without crushing such ingredient.

(b) If canned cherries fall below the standard of fill of container prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard fill specified in § 10.2 (b) of this chapter, in the manner and form therein specified.

§ 27.33 *Canned cherries with rum; identity; label statement of optional ingredients.* Canned cherries with rum conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for canned cherries by § 27.30, except that it contains added rum in such amount that its alcohol content is more than 3 percent but less than 5 percent by weight.

§ 27.40 *Canned fruit cocktail, canned cocktail fruits, canned fruits for cocktail; identity; label statement of optional ingredients.* (a) Canned fruit cocktail, canned cocktail fruits, canned fruits for cocktail, is the food prepared from the mixture of fruit ingredients prescribed in paragraph (b) of this section, in the forms and proportions therein prescribed, and one of the optional packing media specified in paragraph (c) of this section. It is sealed in a container and is so processed by heat as to prevent spoilage.

(b) The fruit ingredients referred to in paragraph (a) of this section, the forms of each, and the percent by weight of each in the mixture of drained fruit from the finished canned fruit cocktail are as follows:

(1) Peaches of any yellow variety, which are pitted, peeled, and diced, not less than 30 percent and not more than 50 percent;

(2) Pears of any variety, which are peeled, cored, and diced, not less than 25 percent and not more than 45 percent;

(3) Whole grapes of any seedless variety, not less than 6 percent and not more than 20 percent;

(4) Pineapples of any variety, which are peeled, cored, and cut into sectors or into dice, not less than 6 percent and not more than 16 percent; and

(5) One of the following optional cherry ingredients, each of which is stemmed, pitted, and cut into approximate halves, not less than 2 percent and not more than 6 percent;

(i) Cherries of any light, sweet variety;

(ii) Cherries artificially colored red; or

(iii) Cherries artificially colored red and artificially flavored.

Each such fruit ingredient is prepared from mature fruit which is fresh or canned. Notwithstanding the preceding provisions of this paragraph, each 4½ ounces avoirdupois of the finished canned fruit cocktail and each fraction thereof greater than 2 ounces avoirdupois contain not less than 2 sectors or 3 dice of pineapple and not less than 1 approximate half of the optional cherry ingredient.

(c) (1) The optional packing media referred to in paragraph (a) of this section are as follows:

(i) Water.
(ii) Fruit juice.
(iii) Light sirup.
(iv) Heavy sirup.
(v) Extra heavy sirup.
(vi) Light fruit juice sirup.
(vii) Heavy fruit juice sirup.
(viii) Extra heavy fruit juice sirup.

(2) Each of packing media (1) (iii), (iv), and (v) is prepared with water as its liquid ingredient, and each of packing media (1) (vi), (vii), and (viii) is prepared with fruit juice as its liquid ingredient. Except as provided in paragraph (d) (6) of this section, each of packing media (1) (iii) to (viii), inclusive, is prepared with any one of the following saccharine ingredients: Sugar; any combination of sugar and dextrose in which the weight of the solids of the dextrose used is not more than one-half the weight of the solids of the sugar used; any combination of sugar and corn sirup or glucose sirup in which the weight of the solids of the corn sirup or glucose sirup used is not more than one-third the weight of the solids of the sugar used; or any combination of sugar, dextrose, and corn sirup or glucose sirup in which the weight of the solids of the dextrose used multiplied by two, added to the weight of the solids of the corn sirup or the glucose sirup used multiplied by three, is not more than the weight of the solids of the sugar used. The respective densities of packing media (1) (iii) to (viii), inclusive, as measured on the Brix hydrometer 15 days or more after the fruit cocktail is canned are within the range prescribed for each in the following list:

Number of packing medium:	Brix measurement
(1) (iii) and (vi)---	14° or more but less than 18°.
(1) (iv) and (vii)--	18° or more but less than 22°.
(1) (v) and (viii)--	22° or more but not more than 35°.

(d) For the purposes of this section:

(1) The term "water" means, in addition to water, both the liquid drained from any fruit ingredient previously canned in water as its sole packing medium and any mixture of water and fruit juice, including the liquid drained from any fruit ingredient previously canned in such mixture.

(2) The term "fruit juice" means the fresh or canned, expressed juice or juices of one or more of the mature fruits named in paragraph (b) of this section including the liquid drained from any fruit ingredient previously canned in such juice or juices as its sole packing medium, to which no water has been added, directly or indirectly. Fruit juice may be strained or filtered.

(3) The term "sugar" means refined sucrose or invert sugar sirup. The term "invert sugar sirup" means an aqueous sirup of inverted or partly inverted, refined or partly refined sucrose, the solids of which contain not more than 0.3 percent by weight of ash and which is colorless, odorless and flavorless except for sweetness.

(4) The term "dextrose" means the hydrated or anhydrous, refined monosaccharide obtained from hydrolyzed starch.

(5) (i) The term "corn sirup" means an aqueous solution obtained by the incomplete hydrolysis of corn starch and includes dried corn sirup; the solids of corn sirup and dried corn sirup contain not less than 58 percent by weight of reducing sugars.

(ii) The term "glucose sirup" means a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch. The solids of glucose sirup contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose. "Dried glucose sirup" means the product obtained by drying "glucose sirup."

(6) When the optional packing medium is prepared with fruit juice and invert sugar sirup or corn sirup other than dried corn sirup or glucose sirup other than dried glucose sirup, it shall be considered to be light sirup, heavy sirup, or an extra heavy sirup, as the case may be, and not a light fruit juice sirup, heavy fruit juice sirup, or an extra heavy fruit juice sirup.

(7) The term "light sirup," "heavy sirup," or "extra heavy sirup" includes a sirup which conforms in all other respects to the provisions of this section, in the preparation of which there is used the liquid drained from any fruit ingredient previously canned in a packing medium consisting wholly of the liquid and saccharine ingredients of a light sirup, heavy sirup, or extra heavy sirup.

(8) Except as provided in subparagraph (6) of this paragraph, the term "light fruit juice sirup," "heavy fruit juice sirup," or "extra heavy fruit juice sirup" includes a sirup which conforms in all other respects to the provisions of this section, in the preparation of which there is used the liquid drained from any fruit ingredients previously canned in a packing medium consisting wholly of the liquid and saccharine ingredients of light fruit juice sirup, heavy fruit juice sirup, or extra heavy fruit juice sirup.

(e) (1) The optional ingredients specified in paragraphs (b) (5) (ii) and (iii) and (c) (1) to (8) of this section, inclusive, are hereby designated as optional ingredients which, when used, shall be named on the label by the name whereby each is so specified.

(2) Such names shall immediately and conspicuously, without intervening written, printed, or graphic matter, precede or follow the name "fruit cocktail," "cocktail fruits," or "fruits for cocktail" wherever it appears on the label so conspicuously as to be easily seen under customary conditions of purchase.

§ 27.41 *Canned fruit cocktail, canned cocktail fruits, canned fruits for cocktail; quality; label statement of substandard quality.* (a) The standard of quality for canned fruit cocktail is as follows:

(1) Not more than 20 percent by weight of the units in the container of peach or pear, or of pineapple if the units thereof are diced, are more than ¾ inch in greatest edge dimension, or pass through the meshes of a sieve designated as 5/16 inch in Table I of "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the National Bureau of Standards, United States Department of Commerce. If the units of pineapple are in the form of sectors, not more than 20 percent of such sectors in the container fail to conform to the following dimensions: The length of the outside arc is not more than ¾ inch but is more than ⅜ inch; the thickness is not more than ½ inch but is more than 5/16 inch; the length (measured along the radius from the inside arc to the outside arc) is not more than 1¼ inches but is more than ¾ inch.

(2) Not more than 10 percent of the grapes in a container containing 10 grapes or more, and not more than 1 grape in a container containing less than 10 grapes, is cracked to the extent of being severed into two parts or is crushed to the extent that their normal shape is destroyed.

(3) Not more than 10 percent of the grapes in a container containing 10 grapes or more, and not more than 1 grape in a container containing less than 10 grapes, has the cap stem attached.

(4) There is present in the finished canned fruit cocktail not more than 1 square inch of pear peel per each 1 pound of drained weight of units of pear

plus the weight of a proportion of the packing medium which is the same proportion as the drained weight of the units of pear bears to the drained weight of the entire contents of the can. Such drained weights shall be determined by the method prescribed in § 27.42.

(5) There is present in the finished canned fruit cocktail not more than 1 square inch of peach peel per each 1 pound of drained weight of units of peach plus the weight of a proportion of the packing medium which is the same proportion as the drained weight of units of peach bears to the drained weight of the entire contents of the can. Such drained weights shall be determined by the method prescribed in § 27.42.

(6) Not more than 15 percent of the units of cherry ingredient, and not more than 20 percent of the units of peach, pear, or grape, in the container is blemished with scab, hail injury, scar tissue, or other abnormality.

(7) If the cherry ingredient is artificially colored, the color of not more than 15 percent of the units thereof in a container containing more than six units, and of not more than one unit in a container containing six units or less, is other than evenly distributed in the unit or other than uniform with the color of the other units of the cherry ingredient.

(b) If the quality of canned fruit cocktail falls below the standard prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard quality specified in § 10.2 (a) of this chapter, in the manner and form therein specified.

§ 27.42 *Canned fruit cocktail, canned cocktail fruits, canned fruits for cocktail; fill of container; label statement of substandard fill.* (a) The standard of fill of container for canned fruit cocktail is a fill such that the total weight of drained fruit is not less than 65 percent of the water capacity of the container, as determined by the general method for water capacity of containers prescribed in § 10.1 (a) of this chapter. Such total weight of drained fruit is determined by the following method: Tilt the opened container so as to distribute the contents evenly over the meshes of a circular sieve which has been previously weighed. The diameter of the sieve is 8 inches if the quantity of contents of the container is less than 3 pounds, and 12 inches if such quantity is 3 pounds or more. The bottom of the sieve is woven-wire cloth which complies with the specifications for such cloth set forth under "2380 Micron (No. 8)" in Table I of "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the United States Department of Commerce, National Bureau of Standards. Without shifting the material on the sieve so incline the sieve as to facilitate drainage. Two minutes from the time drainage begins, weigh the sieve and drained fruit. The weight so found, less the weight of the sieve, shall be considered to be the total weight of drained fruit.

(b) If canned fruit cocktail falls below the standard of fill of container prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard fill specified in § 10.2 (b) of this chapter, in the manner and form therein prescribed.

PART 29—FRUIT BUTTERS, FRUIT JELLIES, FRUIT PRESERVES, AND RELATED PRODUCTS; DEFINITIONS AND STANDARDS OF IDENTITY

Sec.
29.1 Fruit butter; identity; label statement of optional ingredients.
29.2 Fruit jelly; identity; label statement of optional ingredients.
29.3 Preserves, jams; identity; label statement of optional ingredients.

AUTHORITY: §§ 29.1 to 29.3 issued under sec. 701, 52 Stat. 1055; 21 U. S. C. 371. Interpret or apply sec. 401, 52 Stat. 1046, 68 Stat. 54; 21 U. S. C. 341.

§ 29.1 *Fruit butter; identity; label statement of optional ingredients.* (a) The fruit butters for which definitions and standards of identity are prescribed by this section are the smooth, semisolid foods each of which is made from a mixture composed of not less than five parts by weight (as determined by the method prescribed in paragraph (b) (1) of this section) of one or any combination of two, three, four, or five of the optional fruit ingredients specified in paragraph (c) of this section to each two parts by weight (see paragraph (e) (1) of this section) of one of the optional saccharine ingredients specified in paragraph (d) of this section, except that the use of such saccharine ingredient is not required when optional ingredient (5) is used. Such mixture may be seasoned with one or more of the following optional ingredients:

(1) Spice.

(2) Flavoring (other than artificial flavoring).

(3) Salt.

(4) A vinegar, lemon juice, lime juice, citric acid, lactic acid, malic acid, tartaric acid, or any combination of two or more of these.

Such mixture may also contain the optional ingredient:

(5) Fruit juice or diluted fruit juice or concentrated fruit juice, in a quantity not less than one-half the weight of the optional fruit ingredient.

Such mixture is concentrated by heat to such point that the soluble-solids content of the finished fruit butter is not less than 43 percent, as determined by the method prescribed in "Official Methods of Analysis of the Association of Official Agricultural Chemists," Seventh Edition, page 322 [Ed. note, 8th edition, 1955, p. 344, sec. 20.15], under "Soluble Solids in Fresh and Canned Fruits, Jams, Marmalades, and Preserves—First Action," except that no correction is made for water-insoluble solids.

(b) (1) Any requirement of this section with respect to the weight of any optional fruit ingredient, whether concentrated, unconcentrated, or diluted, means the weight determined by the following method:

Determine the percent of soluble solids in the optional fruit ingredient by the method prescribed for determining soluble solids in paragraph (a) of this section; multiply the percent so found by the weight of such ingredient; divide the result by 100; subtract from the quotient the weight of any added sugar or any other added solids; and multiply the remainder by the factor for such ingredient prescribed in paragraph (c) of this section. The result is the weight of the optional fruit ingredient.

(2) For the purposes of this section, the weight of fruit juice or diluted fruit juice or concentrated fruit juice (optional ingredient (a) (5)) from a fruit specified in paragraph (c) of this section is the weight of such juice, as determined by the method prescribed in paragraph (b) (1) of this section, except that the percent of soluble solids is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Agricultural Chemists," Seventh Edition, page 495, [Ed. note, 8th edition, 1955, p. 534, sec. 29.11], under "Solids by Means of Refractometer—Official"; the weight of diluted or concentrated juice from any other fruit is the original weight of the juice before it was diluted or concentrated.

(c) Each of the optional fruit ingredients referred to in paragraph (a) of this section is prepared by cooking one of the following fresh, frozen, canned, and/or dried (evaporated) mature fruits, with or without added water, and screening out skins, seeds, pits, and cores:

Factor referred to in paragraph (b) (1) of this section

Name of fruit:	
Apple	7.5
Apricot	7.0
Grape	7.0
Peach	8.5
Pear	6.5
Plum (other than prune)	7.0
Prune	7.0
Quince	7.5

In any combination of two, three, four, or five fruit ingredients, the weight of each is not less than one-fifth of the weight of the combination.

(d) The optional saccharine ingredients referred to in paragraph (a) of this section are:

(1) Sugar.

(2) Invert sugar sirup.

(3) Brown sugar.

(4) Invert brown sugar sirup.

(5) Honey.

(6) Any combination of two or more of optional saccharine ingredients (1), (2), (3), and (4).

(7) Any combination of dextrose and optional saccharine ingredient (1), (2), (3), (4), or (6).

(8) Any combination composed of corn sirup, dried corn sirup, glucose sirup, dried glucose sirup, or any two or more of the foregoing, with optional saccharine ingredient (1), (2), (3), (4), (6), or (7), in which the weight of the solids of corn sirup, dried corn sirup, glucose sirup, dried glucose sirup, or the sum of the weights of the solids of corn sirup, dried corn sirup, glucose sirup, and dried glucose sirup, in case two or more of these are used, does not exceed one-fourth of the total weight of the solids of the combined saccharine ingredients.

(9) Any combination of honey and optional saccharine ingredient (1), (2), (3), (4), (6), or (7), in which the weight of the solids of each component except

honey is not less than one-tenth of the weight of the solids of such combination, and the weight of honey solids is not less than two-fifths of the weight of the solids of such combination.

(e) For the purposes of this section:

(1) The weight of any optional saccharine ingredient means the weight of the solids of such ingredient.

(2) The term "sugar" means refined sugar (sucrose).

(3) The term "invert sugar sirup" means a sirup made by inverting or partly inverting sugar or partly refined sugar; its ash content is not more than 0.3 percent of its solids content, but if it is made from partly refined sugar, color and flavor other than sweetness are removed.

(4) The term "invert brown sugar sirup" means a sirup made by inverting or partly inverting brown sugar.

(5) The term "corn sirup" means a clarified, concentrated aqueous solution of the products obtained by the incomplete hydrolysis of cornstarch. The solids of corn sirup contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose.

(6) The term "glucose sirup" means a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch. The solids of glucose sirup contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose. "Dried glucose sirup" means the product obtained by drying "glucose sirup."

(7) The term "dextrose" means refined anhydrous or hydrated dextrose made from any starch.

(f) The name of each fruit butter for which a definition and standard of identity is prescribed by this section is as follows:

(1) In case the fruit butter is made from a single fruit ingredient, the name is "Butter," preceded by the name whereby such fruit is designated in paragraph (c) of this section.

(2) In case the fruit butter is made from a combination of two, three, four, or five fruit ingredients, the name is "Butter," preceded by the words "Mixed Fruit" or by the names whereby such fruits are designated in paragraph (c) of this section, in the order of predominance, if any, of the weight of such fruit ingredients in the combination.

(g) (1) When optional ingredient (a) (1) of this section is used, the label shall bear the word "spiced" or the statement "spice added" or "with added spice"; but in lieu of the word "spice" in such statements the common name of the spice may be used.

(2) When optional ingredient (a) (2) of this section is used, the label shall bear the statement "flavoring added" or "with added flavoring." The word "flavoring" in such statements may be preceded by the common name of the kind of flavoring used.

(3) When optional ingredient (a) (5) of this section is used, the label shall bear the words "prepared with -------- juice," the blank to be filled in with the name of the fruit from which the juice is obtained; but if apple juice is used, the word "cider" may be used in lieu of "apple juice."

(4) When optional saccharine ingredient (d) (5) of this section is used, the label shall bear the statement "prepared with honey."

(5) When optional saccharine ingredient (d) (9) is used, the label shall bear the names of the components of the combination whereby such components are designated in paragraph (d) of this section, in the order of predominance, if any, of the weights of such components in the combination. Such name shall be preceded by the words "prepared with."

(6) When the optional fruit ingredient is prepared in whole or in part from dried fruit, the label shall bear the words "prepared from" or "prepared in part from," as the case may be, followed by the word "evaporated" or "dried," followed by the name whereby such fruit is designated in paragraph (c) of this section. When two or more such optional fruit ingredients are used, such names, each preceded by the word "evaporated" or "dried," shall appear in the order of predominance, if any, of the weight of such ingredients in the combination.

(7) When a combination of two, three, four, or five optional fruit ingredients is used, and the fruit butter is designated on its label by the name "Mixed Fruit Butter," the label shall bear the names whereby the fruits from which such ingredients are prepared are designated in paragraph (c) of this section, in the order of predominance, if any, of the weights of such ingredients in the combination.

(8) The label statements required by subparagraphs (1) and (2) of this paragraph may be combined, as for example, "cinnamon oil and cloves added." The label statements required by two or more of subparagraphs (3), (4), (5), (6), and (7) of this paragraph may be combined, as for example, "prepared with cider, apples, dried prunes, and honey."

(h) Wherever the name specified in paragraph (f) of this section appears on the label of the fruit butter so conspicuously as to be easily seen under customary conditions of purchase, the words and statements specified in this section, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter, except that the varietal name of the fruit used in preparing such fruit butter may so intervene.

§ 29.2 *Fruit jelly; identity; label statement of optional ingredients.* (a) The jellies for which definitions and standards of identity are prescribed by this section are the jelled foods each of which is made from a mixture composed of not less than 45 parts by weight (as determined by the method prescribed in paragraph (b) of this section) of one or any combination of two, three, four, or five of the fruit juice ingredients specified in paragraph (c) of this section to each 55 parts by weight (see paragraph (e) (1) of this section) of one of the optional saccharine ingredients specified in paragraph (d) of this section. Such mixture may also contain one or more of the following optional ingredients:

(1) Spice.

(2) A vinegar, lemon juice, lime juice, citric acid, lactic acid, malic acid, tartaric acid, or any combination of two or more of these, in a quantity which reasonably compensates for deficiency, if any, of the natural acidity of the fruit juice ingredient.

(3) Pectin, in a quantity which reasonably compensates for deficiency, if any, of the natural pectin content of the fruit juice ingredient.

(4) Sodium citrate, sodium potassium tartrate, or any combination of these, in a quantity the proportion of which is not more than 3 ounces avoirdupois to each 100 pounds of the saccharine ingredient used.

(5) Sodium benzoate or benzoic acid, or any combination of these, in a quantity reasonably necessary as a preservative.

(6) Mint flavoring and harmless artificial green coloring, in case the fruit juice ingredient or combination of fruit juice ingredients is extracted from apple, crabapple, pineapple, or two or all of such fruits.

Such mixture is concentrated by heat to such point that the soluble-solids content of the finished jelly is not less than 65 percent, as determined by the method prescribed in "Official Methods of Analysis of the Association of Official Agricultural Chemists," Seventh Edition, page 495, [Ed. note, 8th edition, 1955, p. 534, sec. 29.11], under "Solids by Means of Refractometer—Official."

(b) Any requirement of this section with respect to the weight of any fruit juice ingredient, whether concentrated, unconcentrated, or diluted, means the weight determined by the following method: Determine the percent of soluble solids in such fruit juice ingredient by the method for soluble solids referred to in paragraph (a) of this section; multiply the percent so found by the weight of such fruit juice ingredient; divide the result by 100; subtract from the quotient the weight of any added sugar or other added solids; and multiply the remainder by the factor for such fruit juice ingredient prescribed in paragraph (c) of this section. The result is the weight of the fruit juice ingredient.

(c) Each of the fruit juice ingredients referred to in paragraph (a) of this section is the filtered or strained liquid extracted with or without the application of heat and with or without the addition of water, from one of the following mature, properly prepared fruits which are fresh, frozen and/or canned:

Factor referred to in paragraph (b) of this section

Name of fruit:	
Apple	7.5
Apricot	7.0
Blackberry (other than dewberry)	10.0
Black raspberry	9.0
Cherry	7.0
Crabapple	6.5
Cranberry	9.5
Damson, damson plum	7.0
Dewberry (other than boysenberry, loganberry, and youngberry)	10.0
Fig	5.5
Gooseberry	12.0
Grape	7.0
Grapefruit	11.0
Greengage, greengage plum	7.0
Guava	13.0

Factor referred to in paragraph (b) of this section—Continued

Name of fruit—Continued	
Loganberry	9.5
Orange	8.0
Peach	8.5
Pineapple	7.0
Plum (other than damson, greengage, and prune)	7.0
Pomegranate	5.5
Quince	7.5
Raspberry, red raspberry	9.5
Red currant, currant (other than black currant)	9.5
Strawberry	12.5
Youngberry	10.0

In any combination of two, three, four, or five of such fruit juice ingredients the weight of each is not less than one-fifth of the weight of the combination. Each such fruit juice ingredient in any such combination is an optional ingredient.

(d) The optional saccharine ingredients referred to in paragraph (a) of this section are:

(1) Sugar.

(2) Invert sugar sirup.

(3) Any combination composed of optional saccharine ingredients (1) and (2).

(4) Any combination composed of dextrose and optional saccharine ingredient (1), (2), or (3).

(5) Any combination composed of corn sirup, dried corn sirup, glucose sirup, dried glucose sirup, or any two or more of the foregoing, with optional saccharine ingredient (1), (2), (3), or (4), in which the weight of the solids of corn sirup, dried corn sirup, glucose sirup, dried glucose sirup, or the sum of the weights of the solids of corn sirup, dried corn sirup, glucose sirup, and dried glucose sirup, in case two or more of these are used, does not exceed one-fourth of the total weight of the solids of the combined saccharine ingredients.

(6) Honey.

(7) Any combination composed of honey and optional saccharine ingredient (1), (2), or (3), in which the weight of the solids of each component except honey is not less than one-tenth of the weight of the solids of such combination and the weight of honey solids is not less than two-fifths of the weight of the solids of such combination.

(e) For the purposes of this section:

(1) The weight of any optional saccharine ingredient means the weight of the solids of such ingredient.

(2) The term "sugar" means refined sugar (sucrose).

(3) The term "invert sugar sirup" means a sirup made by inverting or partly inverting sugar or partly refined sugar; its ash content is not more than 0.3 percent of its solids content, but if it is made from partly refined sugar, color and flavor other than sweetness are removed.

(4) The term "corn sirup" means a clarified, concentrated aqueous solution of the products obtained by the incomplete hydrolysis of cornstarch. The solids of corn sirup contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose.

(5) The term "glucose sirup" means a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch. The solids of glucose sirup contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose. "Dried glucose sirup" means the product obtained by drying "glucose sirup."

(6) The term "dextrose" means refined anhydrous or hydrated dextrose made from any starch.

(f) The name of each jelly for which a definition and standard of identity is prescribed by this section is as follows:

(1) In case the jelly is made with a single fruit juice ingredient, the name is "Jelly," preceded or followed by the name or synonym whereby the fruit from which such fruit juice ingredient was extracted is designated in paragraph (c) of this section.

(2) In case the jelly is made with a combination of two, three, four, or five fruit juice ingredients, the name is "Jelly," preceded or followed by the words "Mixed Fruit" or by the names or synonyms whereby the fruits from which the fruit juice ingredients were extracted are designated in paragraph (c) of this section, in the order of predominance, if any, of the weights of such fruit juice ingredients in the combination.

(g) (1) When optional ingredient (a) (1) is used, the label shall bear the word "spiced" or the statement "spice added" or "with added spice"; but in lieu of the word "spice" in such statements the common name of the spice may be used.

(2) When optional ingredient (a) (5) is used, the label shall bear the words "sodium benzoate" or "benzoic acid" or "sodium benzoate and benzoic acid," as the case may be, followed by the words "added as preservative."

(3) When optional ingredient (a) (6) is used, the label shall bear the statement "flavoring and artificial coloring added" or "with added flavoring and artificial coloring." The word "flavoring" in such statement may be preceded by the word "mint."

(4) When optional saccharine ingredient (d) (7) is used, the label shall bear the names of the components of the combination whereby such components are designated in paragraph (d) of this section, in the order of predominance, if any, of the weight of such components in the combination. Such names shall be preceded by the words "prepared with."

(5) When optional saccharine ingredient (d) (6) is used, the label shall bear the statement "prepared with honey."

(6) When a combination of two, three, four, or five fruit juice ingredients is used, and the jelly is designated on its label by the word "Jelly," preceded or followed by the words "Mixed Fruit," the label shall bear the names or synonyms whereby such fruits are designated in paragraph (c) of this section, in the order of predominance, if any, of the weights of such fruit juice ingredients in the combination.

(h) Wherever the name specified in paragraph (f) of this section appears on the label of the jelly so conspicuously as to be easily seen under customary conditions of purchase, the words and statements herein specified, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter, except that the varietal name of the fruit used in preparing such jelly may so intervene.

§ 29.3 *Preserves, jams; identity; label statement of optional ingredients.* (a) The preserves or jams for which definitions and standards of identity are prescribed by this section are the viscous or semisolid foods each of which is made from a mixture composed of not less than 45 parts by weight (see paragraph (c) of this section) of one of the fruit ingredients specified in paragraph (b) of this section to each 55 parts by weight (see paragraph (e) (1) of this section) of one of the optional saccharine ingredients specified in paragraph (d) of this section. Such mixture may also contain one or more of the following optional ingredients:

(1) Spice.

(2) A vinegar, lemon juice, lime juice, citric acid, lactic acid, malic acid, tartaric acid, or any combinaton of two or more of these, in a quantity which reasonably compensates for deficiency, if any, of the natural acidity of the fruit ingredient.

(3) Pectin, in a quantity which reasonably compensates for deficiency, if any, of the natural pectin content of the fruit ingredient.

(4) Sodium citrate, sodium potassium tartrate, or any combination of these, in a quantity the proportion of which is not more than 3 ounces avoirdupois to each 100 pounds of the saccharine ingredient used.

(5) Sodium benzoate or benzoic acid or any combination of these, in a quantity reasonably necessary as a preservative.

Such mixture, with or without added water, is concentrated by heat to such point that the soluble-solids content of the finished preserve is not less than 68 percent if the fruit ingredient is specified in Group I of paragraph (b) of this section, and not less than 65 percent if the fruit ingredient is specified in Group II of paragraph (b) of this section. The soluble-solids content is determined by the method prescribed in "Official Methods of Analysis of the Association of Official Agricultural Chemists," Seventh Edition, page 322 [Ed. note, 8th edition, 1955, p. 344, sec. 20.15], under "Soluble Solids in Fresh and Canned Fruits, Jams, Marmalades, and Preserves—First Action," except that no correction is made for water-insoluble solids.

(b) The fruit ingredients referred to in paragraph (a) of this section are the following mature, properly prepared fruits which are fresh, frozen and/or canned:

GROUP I

Blackberry (other than dewberry).
Black raspberry.
Blueberry.
Boysenberry.
Cherry.
Crabapple.
Dewberry (other than boysenberry, loganberry, and youngberry).
Elderberry.
Grape.
Grapefruit.

GROUP I—Continued

Huckleberry.
Loganberry.
Orange.
Pineapple.
Raspberry, red raspberry.
Rhubarb.
Strawberry.
Tangerine.
Tomato.
Yellow tomato.
Youngberry.

Any combination of two, three, four, or five of such fruits in which the weight of each is not less than one-fifth of the weight of the combination; except that the weight of pineapple may be not less than one-tenth of the weight of the combination.

GROUP II

Apricot.
Cranberry.
Damson, damson plum.
Fig.
Gooseberry.
Greengage, greengage plum.
Guava.
Nectarine.
Peach.
Pear.
Plum (other than greengage plum and damson plum).
Quince.
Red currant, currant (other than black currant).

Any combination of two, three, four, or five of such fruits, or one or more of such fruits with one or more of the individual fruits specified in Group I, in which the weight of each is not less than one-fifth of the weight of the combination; except that the weight of pineapple may be not less than one-tenth of the weight of the combination.

Any combination of apple and one, two, three, or four of the individual fruits specified in this group or Group I in which the weight of each is not less than one-fifth, and the weight of apple is not more than one-half, of the weight of the combination; except that the weight of pineapple may be not less than one-tenth of the weight of the combination.

In any combination of two, three, four, or five fruits, each such fruit is an optional ingredient. For the purposes of this section, the word "fruit" includes the vegetables specified in this paragraph.

(c) Any requirement of this section with respect to the weight of any fruit, combination of fruits, or fruit ingredient means:

(1) The weight of fruit exclusive of the weight of any sugar, water, or other substance added for any processing or packing or canning, or otherwise added to such fruit;

(2) In the case of fruit prepared by the removal, in whole or in part, of pits, seeds, skins, cores, or other parts, the weight of such fruit, exclusive of the weight of all such substances removed therefrom; and

(3) In the cases of apricots, cherries, grapes, nectarines, peaches, and all varieties of plums, whether or not pits and seeds are removed therefrom, the weight of such fruit, exclusive of the weight of such pits and seeds.

(d) The optional saccharine ingredients referred to in paragraph (a) of this section are:

(1) Sugar.

(2) Invert sugar sirup.

(3) Any combination composed of optional saccharine ingredients (1) and (2).

(4) Any combination composed of dextrose and optional saccharine ingredient (1), (2), or (3).

(5) Any combination composed of corn sirup, dried corn sirup, glucose sirup, dried glucose sirup, or any two or more of the foregoing, with optional saccharine ingredient (1), (2), (3), or (4), in which the weight of the solids of corn sirup, dried corn sirup, glucose sirup, dried glucose sirup, or the sum of the weights of the solids of corn sirup, dried corn sirup, glucose sirup, and dried glucose sirup, in case two or more of these are used, does not exceed one-fourth of the total weight of the solids of the combined saccharine ingredients.

(6) Honey.

(7) Any combination composed of honey and optional saccharine ingredient (1), (2), or (3), in which the weight of the solids of each component except honey is not less than one-tenth of the weight of the solids of such combination and the weight of honey solids is not less than two-fifths of the weight of the solids of such combination.

(e) For the purposes of this section:

(1) The weight of any optional saccharine ingredient means the weight of the solids of such ingredient.

(2) The term "sugar" means refined sugar (sucrose).

(3) The term "invert sugar sirup" means a sirup made by inverting or partly inverting sugar or partly refined sugar; its ash content is not more than 0.3 percent of its solids content, but if it is made from partly refined sugar, color and flavor other than sweetness are removed.

(4) The term "corn sirup" means a clarified, concentrated aqueous solution of the products obtained by incomplete hydrolysis of cornstarch. The solids of corn sirup contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose.

(5) The term "glucose sirup" means a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch. The solids of glucose sirup contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose. "Dried glucose sirup" means the product obtained by drying "glucose sirup."

(6) The term "dextrose" means refined anhydrous or hydrated dextrose made from any starch.

(f) The name of each preserve or jam for which a definition and standard of identity is prescribed by this section is as follows:

(1) If the fruit ingredient is a single fruit, the name is "Preserve" or "Jam," preceded or followed by the name or synonym whereby such fruit is designated in paragraph (b) of this section.

(2) If the fruit ingredient is a combination of two, three, four, or five fruits, the name is "Preserve" or "Jam," preceded or followed by the words "Mixed Fruit" or by the names or synonyms whereby such fruits are designated in paragraph (b) of this section, in the order of predominance, if any, of the weights of such fruits in the combination.

(g) (1) When optional ingredient (a) (1) is used, the label shall bear the word "spiced" or the statement "spice added" or "with added spice"; but in lieu of the word "spice" in such statements the common name of the spice may be used.

(2) When optional ingredient (a) (5) is used, the label shall bear the words "sodium benzoate" or "benzoic acid," or "sodium benzoate and benzoic acid," as the case may be, followed by the words "added as preservative."

(3) When optional saccharine ingredient (d) (7) is used, the label shall bear the names of the components of the combination whereby such components are designated in paragraph (d) of this section, in the order of predominance, if any, of the weights of such components in the combination. Such names shall be preceded by the words "prepared with."

(4) When optional saccharine ingredient (d) (6) is used, the label shall bear the statement "prepared with honey."

(5) When the fruit ingredient is a combination of two, three, four, or five fruits and the preserve is designated on its label by the name "Preserve" or "Jam," preceded or followed by the words "Mixed Fruit," the label shall bear the names or synonyms whereby such fruits are designated in paragraph (b) of this section, in the order of predominance, if any, of the weights of such fruits in the combination.

(h) Wherever the name specified in paragraph (f) of this section appears on the label of the preserve so conspicuously as to be easily seen under customary conditions of purchase, the words and statements herein specified, showing the optional ingredients used, shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter, except that the varietal name of the fruit used in preparing such preserve may so intervene.

PART 36—SHELLFISH; DEFINITIONS AND STANDARDS OF IDENTITY; FILL OF CONTAINER

CANNED SHRIMP

Sec.
36.3 Canned wet pack shrimp and canned dry pack shrimp in nontransparent containers; fill of container; label statement of substandard fill.

CANNED OYSTERS

36.5 Canned oysters; identity; label statement of optional ingredients.
36.6 Canned oysters; fill of container; label statement of substandard fill.

RAW OYSTERS

36.10 Oysters, raw oysters, shucked oysters; identity.
36.11 Extra large oysters, oysters counts (or plants), extra large raw oysters, raw oysters counts (or plants), extra large shucked oysters, shucked oysters counts (or plants); identity.
36.12 Large oysters, oysters extra selects, large raw oysters, raw oysters extra selects, large shucked oysters, shucked oysters extra selects; identity.

Sec.
36.13 Medium oysters, oysters selects, medium raw oysters, raw oysters selects, medium shucked oysters, shucked oysters selects; identity.
36.14 Small oysters, oysters standards, small raw oysters, raw oysters standards, small shucked oysters, shucked oysters standards; identity.
36.15 Very small oysters, very small raw oysters, very small shucked oysters; identity.
36.16 Olympia oysters, raw Olympia oysters, shucked Olympia oysters; identity.

PACIFIC OYSTERS

36.17 Large Pacific oysters, large raw Pacific oysters, large shucked Pacific oysters; identity.
36.18 Medium Pacific oysters, medium raw Pacific oysters, medium shucked Pacific oysters; identity.
36.19 Small Pacific oysters, small raw Pacific oysters, small shucked Pacific oysters; identity.
36.20 Extra small Pacific oysters, extra small raw Pacific oysters, extra small shucked Pacific oysters; identity.

AUTHORITY: §§ 36.3 to 36.20 issued under sec. 701 (a), 52 Stat. 1055; 21 U. S. C. 371 (a). Interpret or apply sec. 401, 52 Stat. 1046, 68 Stat. 54; 21 U. S. C. 341.

CANNED SHRIMP

§ 36.3 *Canned wet pack shrimp and canned dry pack shrimp in nontransparent containers; fill of container; label statement of substandard fill.* (a) The standard of fill of nontransparent containers for canned wet pack shrimp is a fill such that the cut-out weight of shrimp taken from each can is not less than 64 percent of the water capacity of the container, and, for canned dry pack shrimp (except that packed in the nontransparent cylindrical container which is $2^{11}/_{16}$ inches in diameter and 4 inches in height), is a fill such that the cut-out weight of shrimp taken from each can is not less than 60 percent of the water capacity of the container. The standard of fill for canned dry pack shrimp packed in the nontransparent cylindrical container which is $2^{11}/_{16}$ inches in diameter and 4 inches in height is a cut-out weight of not less than $6\frac{1}{2}$ avoirdupois ounces of shrimp for each container. Water capacity of containers is determined by the general method provided in § 10.1 (a) of this chapter. Cut-out weight is determined by the following method:

Keep the unopened canned shrimp container at a temperature of not less than 68° nor more than 95° Fahrenheit for at least 12 hours immediately preceding the determination. After opening, tilt the container so as to distribute the shrimp evenly over the meshes of a circular sieve which has been previously weighed. The diameter of the sieve is 8 inches if the quantity of the contents of the container is less than 3 pounds, and 12 inches if such quantity is 3 pounds or more. The bottom of the sieve is woven-wire cloth which complies with the specifications for such cloth set forth under "2380 Micron (No. 8)" in Table I of "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the United States Department of Commerce, National Bureau of Standards. Without shifting the material on the sieve, so incline the sieve as to facilitate drainage. Two minutes from the time drainage begins, weigh the sieve and the drained shrimp. The weight so found, less the weight of the sieve, shall be considered to be the cut-out weight of the shrimp.

(b) If canned wet pack shrimp or canned dry pack shrimp, in nontransparent containers, falls below the applicable standard of fill of container prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard fill provided in § 10.2 (b) of this chapter, in the manner and form therein specified.

CANNED OYSTERS

§ 36.5 *Canned oysters; identity; label statement of optional ingredients.* (a) Canned oysters is the food prepared from one or any mixture of two or all of the forms of oysters specified in paragraph (b) of this section, and a packing medium of water, or the watery liquid draining from oysters before or during processing, or a mixture of such liquid and water. The food may be seasoned with salt. It is sealed in containers and so processed by heat as to prevent spoilage.

(b) The forms of oysters referred to in paragraph (a) of this section are prepared from oysters which have been removed from their shells and washed and which may be steamed while in the shell or steamed or blanched or both after removal therefrom, and are as follows:

(1) Whole oysters with such broken pieces of oysters as normally occur in removing oysters from their shells, washing, and packing.

(2) Pieces of oysters obtained by segregating pieces of oysters broken in shucking, washing, or packing whole oysters.

(3) Cut oysters obtained by cutting whole oysters.

(c) (1) When the form of oysters specified in paragraph (b) (1) of this section is used, the name of the food is "Oysters" or "Cove Oysters," if of the species Ostrea virginica; "Oysters" or "Pacific Oysters," if of the species Ostrea gigas; "Oysters" or "Olympia Oysters," if of the species Ostrea lurida.

(2) When the form of oysters specified in paragraph (b) (2) of this section is used, the name of the food is "Pieces of ______," the blank being filled in with the name "Oysters" or "Cove Oysters," if of the species Ostrea virginica; "Oysters" or "Pacific Oysters," if of the species Ostrea gigas; "Oysters" or "Olympia Oysters," if of the species Ostrea lurida.

(3) When the form of oysters specified in paragraph (b) (3) of this section is used, the name of the food is "Cut ____," the blank being filled in with the name "Oysters" or "Cove Oysters," if of the species Ostrea virginica; "Oysters" or "Pacific Oysters," if of the species Ostrea gigas; "Oysters" or "Olympia Oysters," if of the species Ostrea lurida.

(4) In case a mixture of two or all such forms of oysters is used, the name is a combination of the names specified in this paragraph of the forms of oysters used, arranged in order of their predominance by weight.

§ 36.6 *Canned oysters; fill of container; label statement of substandard fill.* (a) The standard of fill of container for canned oysters is a fill such that the drained weight of oysters taken from each container is not less than 59 percent of the water capacity of the container.

(b) Water capacity of containers is determined by the general method provided in § 10.1 (a) of this chapter.

(c) Drained weight is determined by the following method:

Keep the unopened canned oyster container at a temperature of not less than 68° or more than 95° Fahrenheit for at least 12 hours immediately preceding the determination. After opening, tilt the container so as to distribute its contents evenly over the meshes of a circular sieve which has been previously weighed. The diameter of the sieve is 8 inches if the quantity of the contents of the container is less than 3 pounds, and 12 inches if such quantity is 3 pounds or more. The bottom of the sieve is woven-wire cloth which complies with the specifications for such cloth set forth under "2380 Micron (No. 8)," in Table I of "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the United States Department of Commerce, National Bureau of Standards. Without shifting the material on the sieve, so incline the sieve as to facilitate drainage. Two minutes from the time drainage begins, weigh the sieve and the drained oysters. The weight so found, less the weight of the sieve, shall be considered to be the drained weight of the oysters.

(d) If canned oysters fall below the standard of fill of container prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard fill specified in § 10.2 (b) of this chapter in the manner and form therein specified, followed by the statement, "A can of this size should contain ______ oz. of oysters. This can contains only ______ oz.," the blanks being filled in with the applicable figures.

RAW OYSTERS

§ 36.10 *Oysters, raw oysters, shucked oysters; identity.* (a) Oysters, raw oysters, shucked oysters, are the class of foods each of which is obtained by shucking shell oysters and preparing them in accordance with the procedure prescribed in paragraph (b) of this section. The name of each such food is the name specified in the applicable definition and standard of identity prescribed in §§36.11 to 36.22, inclusive.

(b) If water, or salt water containing less than 0.75 percent salt, is used in any vessel into which the oysters are shucked, the combined volume of oysters and liquid when such oysters are emptied from such vessel is not less than four times the volume of such water or salt water. Any liquid accumulated with the oysters is removed. The oysters are washed, by blowing or otherwise, in water or salt water, or both. The total time that the oysters are in contact with water or salt water after leaving the shucker, including the time of washing, rinsing, and any other contact with water or salt water is not more than 30 minutes. In computing the time of contact with water or salt water, the length of time that oysters are in contact with water or salt water that is agitated by blowing or otherwise, shall be calculated at twice its actual length. Any period of time that oysters are in contact with salt water containing not less than 0.75 percent salt before contact with oysters, shall not be included in computing the time that the oysters are in contact with water or salt water. Before packing into the containers for shipment or other delivery for consumption the oysters are thoroughly drained and are packed without any added substance.

(c) For the purposes of this section:

(1) "Shell oysters" means live oysters of any of the species, Ostrea virginica, Ostrea gigas, Ostrea lurida, in the shell, which, after removal from their beds, have not been floated or otherwise held under conditions which result in the addition of water.

(2) "Thoroughly drained" means one of the following:

(i) The oysters are drained on a strainer or skimmer which has an area of not less than 300 square inches per gallon of oysters, drained, and has perforations of at least ¼ of an inch in diameter and not more than 1¼ inches apart, or perforations of equivalent areas and distribution. The oysters are distributed evenly over the draining surface of the skimmer and drained for not less than 5 minutes; or

(ii) The oysters are drained by any method other than that prescribed by subdivision (i) of this subparagraph whereby liquid from the oysters is removed so that when the oysters are tested within 15 minutes after packing by draining a representative gallon of oysters on a skimmer of the dimensions and in the manner described in subdivision (i) of this subparagraph for 2 minutes, not more than 5 percent of liquid by weight is removed by such draining.

§ 36.11 *Extra large oysters, oysters counts (or plants), extra large raw oysters, raw oysters counts (or plants), extra large shucked oysters, shucked oysters counts (or plants); identity.* Extra large oysters, oysters counts (or plants), extra large raw oysters, raw oysters counts (or plants), extra large shucked oysters, shucked oysters counts (or plants), are of the species Ostrea virginica and conform to the definition and standard of identity prescribed for oysters by § 36.10 and are of such size that 1 gallon contains not more than 160 oysters and a quart of the smallest oysters selected therefrom contains not more than 44 oysters.

§ 36.12 *Large oysters, oysters extra selects, large raw oysters, raw oysters extra selects, large shucked oysters, shucked oysters extra selects; identity.* Large oysters, oysters extra selects, large raw oysters, raw oysters extra selects, large shucked oysters, shucked oysters extra selects, are of the species Ostrea virginica and conform to the definition and standard of identity prescribed for oysters by § 36.10 and are of such size that 1 gallon contains more than 160 oysters but not more than 210 oysters; a quart of the smallest oysters selected therefrom contains not more than 58 oysters, and a quart of the largest oysters selected therefrom contains more than 36 oysters.

§ 36.13 *Medium oysters, oysters selects, medium raw oysters, raw oysters selects, medium shucked oysters, shucked oysters selects; identity.* Medium oysters, oysters selects, medium raw oysters, raw oysters selects, medium shucked oysters, shucked oysters selects, are of the species Ostrea virginica and conform to the definition and standard of identity prescribed for oysters by § 36.10 and are of such size that 1 gallon contains more than 210 oysters, but not more than 300 oysters; a quart of the smallest oysters selected therefrom contains not more than 83 oysters, and a quart of the largest oysters selected therefrom contains more than 46 oysters.

§ 36.14 *Small oysters, oysters standards, small raw oysters, raw oysters standards, small shucked oysters, shucked oysters standards; identity.* Small oysters, oysters standards, small raw oysters, raw oysters standards, small shucked oysters, shucked oysters standards, are of the species Ostrea virginica and conform to the definition and standards of identity prescribed for oysters by § 36.10 and are of such size that 1 gallon contains more than 300 oysters but not more than 500 oysters; a quart of the smallest oysters selected therefrom contains not more than 138 oysters and a quart of the largest oysters selected therefrom contains more than 68 oysters.

§ 36.15 *Very small oysters, very small raw oysters, very small shucked oysters; identity.* Very small oysters, very small raw oysters, very small shucked oysters, are of the species Ostrea virginica and conform to the definition and standard of identity prescribed for oysters by § 36.10 and are of such size that 1 gallon contains more than 500 oysters, and a quart of the largest oysters selected therefrom contains more than 112 oysters.

§ 36.16 *Olympia oysters, raw Olympia oysters, shucked Olympia oysters; identity.* Olympia oysters, raw Olympia oysters, shucked Olympia oysters, are of the species Ostrea lurida and conform to the definition and standard of identity prescribed for oysters in § 36.10.

PACIFIC OYSTERS

§ 36.17 *Large Pacific oysters, large raw Pacific oysters, large shucked Pacific oysters; identity.* Large Pacific oysters, large raw Pacific oysters, large shucked Pacific oysters, are of the species Ostrea gigas and conform to the definitions and standards of identity prescribed for oysters by § 36.10 and are of such size that 1 gallon contains not more than 64 oysters, and the largest oyster in the container is not more than twice the weight of the smallest oyster therein.

§ 36.18 *Medium Pacific oysters, medium raw Pacific oysters, medium shucked Pacific oysters; identity.* Medium Pacific oysters, medium raw Pacific oysters, medium shucked Pacific oysters, are of the species Ostrea gigas and conform to the definition and standard of identity prescribed for oysters by § 36.10 and are of such size that 1 gallon contains more than 64 oysters and not more than 96 oysters, and the largest oyster in the container is not more than twice the weight of the smallest oyster therein.

§ 36.19 *Small Pacific oysters, small raw Pacific oysters, small shucked Pacific oysters; identity.* Small Pacific oysters, small raw Pacific oysters, small shucked Pacific oysters, are of the species Ostrea gigas and conform to the definition and standard of identity prescribed for oysters by § 36.10 and are of such size that 1 gallon contains more than 96 oysters and not more than 144 oysters, and the largest oyster in the container is not more than twice the weight of the smallest oyster therein.

§ 36.20 *Extra small Pacific oysters, extra small raw Pacific oysters, extra small shucked Pacific oysters; identity.* Extra small Pacific oysters, extra small raw Pacific oysters, extra small shucked Pacific oysters, are of the species Ostrea gigas and conform to the definition and standard of identity prescribed for oysters by § 36.10 and are of such size that 1 gallon contains more than 144 oysters, and the largest oyster in the container is not more than twice the weight of the smallest oyster therein.

PART 42—EGGS AND EGG PRODUCTS; DEFINITIONS AND STANDARDS OF IDENTITY

Sec.

42.1 Eggs.
42.10 Liquid eggs, mixed eggs, liquid whole eggs, mixed whole eggs; identity.
42.20 Frozen eggs, frozen whole eggs, frozen mixed eggs; identity.
42.30 Dried eggs, dried whole eggs; identity.
42.40 Egg yolks, liquid egg yolks, yolks, liquid yolks; identity.
42.50 Frozen yolks, frozen egg yolks; identity.
42.60 Dried egg yolks, dried yolks; identity.

AUTHORITY: §§ 42.1 to 42.60 issued under sec. 701 (a), 52 Stat. 1055; 21 U. S. C. 371 (a). Interpret or apply sec. 401, 52 Stat. 1046, 68 Stat. 54; 21 U. S. C. 341.

§ 42.1 *Eggs.* No regulation shall be promulgated fixing and establishing a reasonable definition and standard of identity for the food commonly known as eggs.

§ 42.10 *Liquid eggs, mixed eggs, liquid whole eggs, mixed whole eggs; identity.* Liquid eggs, mixed eggs, liquid whole eggs, mixed whole eggs, are eggs of the domestic hen, broken from the shells, and with yolks and whites in their natural proportions as so broken. They may be mixed, or mixed and strained.

§ 42.20 *Frozen eggs, frozen whole eggs, frozen mixed eggs; identity.* Frozen eggs, frozen whole eggs, frozen mixed eggs, are the food prepared by freezing liquid eggs.

§ 42.30 *Dried eggs, dried whole eggs; identity.* Dried eggs, dried whole eggs, are the food prepared by drying liquid eggs. They may be powdered. They contain not less than 92 percent total egg solids, as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fourth Edition, 1935, pages 297 and 298 [Ed. note, 8th edition, 1955, p. 291–292, secs. 16.2, 16.3], under "Total Solids."

§ 42.40 *Egg yolks, liquid egg yolks, yolks, liquid yolks; identity.* Egg yolks, liquid egg yolks, yolks, liquid yolks, are yolks of eggs of the domestic hen so separated from the whites thereof as to contain not less than 43 percent total egg solids, as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fourth Edition, 1935, pages 297 and 298 [Ed. note, 8th edition, 1955, p. 291–292, secs. 16.2, 16.3], under "Total Solids." They may be mixed, or mixed and strained.

§ 42.50 *Frozen yolks, frozen egg yolks; identity.* Frozen yolks, frozen egg yolks, are the food prepared by freezing egg yolks.

§ 42.60 *Dried egg yolks, dried yolks; identity.* Dried egg yolks, dried yolks, are the food prepared by drying egg yolks. They contain not less than 95 percent total egg solids, as determined by the method prescribed in "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fourth Edition, 1935, pages 297 and 298 [Ed. note, 8th edition, 1955, p. 291–292, secs. 16.2, 16.3], under "Total Solids."

PART 45—OLEOMARGARINE, MARGARINE; DEFINITION AND STANDARD OF IDENTITY

§ 45.1 *Oleomargarine, margarine; identity; label statement of optional ingredients.* (a) Oleomargarine, margarine is the plastic food prepared with one or more of the optional fat ingredients named in subparagraph (1) (i), (ii), (iii), and (iv) of this paragraph, as follows:

(1) (i) The rendered fat or oil, or stearin derived therefrom (any or all of which may be hydrogenated), of cattle, sheep, swine, or goats, or any combination of two or more of such articles.

(ii) Any vegetable food fat or oil, or oil or stearin derived therefrom (any or all of which may be hydrogenated), or any combination of two or more of such articles.

(iii) Any combination of ingredients named in subdivisions (i) and (ii) of this subparagraph, in such proportion that the weight of the ingredients named in subdivision (i) either equals the weight of the ingredients named in subdivision (ii), or exceeds such weight by a ratio of not greater than 9 to 1.

(iv) Any combination of ingredients named in subdivisions (i) and (ii) of this subparagraph, in such proportion that the weight of the ingredients named in subdivision (ii) exceeds the weight of the ingredients named in subdivision (i) by a ratio not greater than 9 to 1.

(2) One of the articles designated in subdivision (i), (ii), (iii), (iv), (v), or (vi) of this subparagraph is intimately mixed with the fat ingredient or ingredients. The ingredients named in subdivisions (i), (ii), (iii), (iv), and (v) are pasteurized and then subjected to the action of harmless bacterial starters. The term "milk" as used in this subparagraph means cow's milk.

(i) Cream.

(ii) Milk.

(iii) Skim milk.

(iv) Any combination of nonfat dry milk solids and water, in which the weight of the nonfat dry milk solids is not less than 10 percent of the weight of the water.

(v) Any mixture of two or more of the articles named in subdivisions (i), (ii), (iii), and (iv).

(vi) In case only of the fat ingredient designated in subparagraph (1) (ii) of this paragraph, any combination of finely ground soybeans and water, in which the weight of the finely ground soybeans is not less than 10 percent of the weight of the water. The finely ground soybeans are subjected to a heat treatment before or after mixing with the water. The soybeans may or may not be dehulled.

Congealing is effected, either with or without contact with water, and the congealed mixture may be worked.

(3) In the preparation of oleomargarine one or more of the following optional ingredients may also be used:

(i) Artificial coloring. For the purposes of this subdivision provitamin A shall be deemed to be artificial coloring.

(ii) Sodium benzoate or benzoic acid or a combination of these, in a quantity not to exceed 0.1 percent of the weight of the finished product.

(iii) Vitamin A (with or without any accompanying vitamin D and with or without vitamin D concentrate), in such quantity that the finished oleomargarine contains not less than 15,000 United States Pharmacopeia units of vitamin A per pound, as determined by the method prescribed in the Pharmacopeia of the United States for total biological vitamin A activity. The vitamin A potency prescribed may be furnished by fish liver oil; by concentrates of vitamin A or its fatty acid esters from animal sources; by synthetic vitamin A or its fatty acid esters; by mixtures of synthetic vitamin A or its fatty acid esters with harmless substances formed during the synthesis of the vitamin A, if the vitamin A or its fatty acid ester constitutes not less than 50 percent of the mixture; by provitamin A; or by any combination of two or more of these. For the purposes of this subdivision the term "fatty acid" may include acetic acid.

(iv) The artificial flavoring diacetyl added as such or as starter distillate or produced during the preparation of the product as a result of the addition of citric acid or harmless citrates.

(v) (*a*) Lecithin, in an amount not exceeding 0.5 percent of the weight of the finished oleomargarine; or

(*b*) Monoglycerides or diglycerides of fat-forming fatty acids, or a combination of these, in an amount not exceeding 0.5 percent of the weight of the finished oleomargarine; or

(*c*) Such monoglycerides and diglycerides in combination with the sodium sulfo-acetate derivatives thereof, in a total amount not exceeding 0.5 percent of the weight of the finished oleomargarine; or

(*d*) A combination of (*a*) and (*b*) of this subdivision, in which the amount of neither exceeds that above stated; or

(*e*) A combination of (*a*) and (*c*) of this subdivision, in a total amount not exceeding 0.5 percent of the weight of the finished oleomargarine.

The weight of the diglycerides in each of ingredients (*b*), (*c*), (*d* , and (*e*) of this subdivision is calculated at one-half actual weight.

(vi) Butter.

(vii) Salt.

(viii) Citric acid incorporated in the fat or oil ingredient used.

(ix) Isopropyl citrates incorporated in the fat or oil ingredient used, in an amount not to exceed 0.02 percent by weight of the finished oleomargarine.

(x) Stearyl citrate incorporated in the fat or oil ingredient used, in an amount not to exceed 0.15 percent by weight of the finished oleomargarine.

The finished oleomargarine contains not less than 80 percent fat, as determined by the method prescribed in "Official Methods of Analysis of the Association of Official Agricultural Chemists," 7th Edition, page 259 under "Indirect Method," section 15.111. [Ed. note, 8th edition, 1955, p. 271, sec. 15.109.]

(b) (1) When any ingredient named under one of the following specified subparagraphs of paragraph (a) of this section is used, the label shall, except as provided in this paragraph, bear the statement set forth below after the number of such subparagraph:

Subparagraph (1) (i)—"Prepared from Animal Fat" or "Made from Animal Fat."

Subparagraph (1) (ii)—"Vegetable" or "Prepared from Vegetable Fat" or "Made from Vegetable Fat."

Subparagraph (2) (vi)—In lieu of label statement prescribed for ingredients designated in subparagraph (1) (ii), "Prepared from Vegetable Fat, Water and Finely Ground Soybeans" or "Made from Vegetable Fat, Water and Finely Ground Soybeans."

Subparagraph (1) (iii)—"Prepared from Animal and Vegetable Fats" or "Made from Animal and Vegetable Fats."

Subparagraph (1) (iv)—"Prepared from Vegetable and Animal Fats" or "Made from Vegetable and Animal Fats."

Subparagraph (3) (i)—"Artificially Colored" or "Artificial Coloring Added" or "With Added Artificial Coloring."

Subparagraph (3) (ii)—"Sodium Benzoate (or, as the case may be, "Benzoic Acid" or "Sodium Benzoate and Benzoic Acid") Added as a Preservative" or "With Added Sodium Benzoate (or, as the case may be, "Benzoic Acid" or "Sodium Benzoate and Benzoic Acid") as a Preservative."

Subparagraph (3) (iii)—"Vitamin A Added" or "With Added Vitamin A."

Subparagraph (3) (iv)—"Artificially Flavored" or "Artificial Flavoring Added" or "With Added Artificial Flavoring."

Subparagraph (3) (viii)—"Citric Acid Added to Protect Flavor" or "Citric Acid Added as a Preservative."

Subparagraph (3) (ix)—"Isopropyl Citrate Added to Protect Flavor" or "Isopropyl Citrate Added as a Preservative."

Subparagraph (3) (x)—"Stearyl Citrate Added to Protect Flavor" or "Stearyl Citrate Added as a Preservative."

Where oil is used, the word "oil" may be substituted for "fat" in the label statement. In lieu of the word "animal" or "vegetable" in any such statement, the common or usual name of the fat ingredient may be used. If two or more of the optional ingredients named in paragraph (a) (3) (i), (ii), (iii), (iv), (viii), (ix), and (x) of this section are used, the words "added" or "with added" need appear only once, either at the beginning or end of the list of such ingredients declared. The declaration of vitamin A may include the number of United States Pharmacopeia units present in the finished oleomargarine.

(2) Wherever the name "oleomargarine" or "margarine" appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed in this section, showing the ingredients used, shall immediately and conspicuously precede or follow, or in part precede and in part follow, such name, without intervening written, printed, or other graphic matter.

(Sec. 701 (a), 52 Stat. 1055; 21 U. S. C. 371 (a). Interprets or applies sec. 401, 52 Stat. 1046, 68 Stat. 54; 21 U. S. C. 341)

PART 51—CANNED VEGETABLES; DEFINITIONS AND STANDARDS OF IDENTITY; QUALITY; AND FILL OF CONTAINER

CANNED PEAS

Sec.
51.1 Identity; label statement of optional ingredients.
51.2 Quality; label statement of substandard quality.
51.3 Fill of container; label statement of substandard fill.

CANNED BEANS

51.10 Canned green beans; identity; label statement of optional ingredients.
51.11 Canned green beans; quality; label statement of substandard quality.
51.15 Canned wax beans; identity; label statement of optional ingredients.
51.16 Canned wax beans; quality; label statement of substandard quality.

CANNED CORN

51.20 Canned corn, canned sweet corn, canned sugar corn; identity; label statement of optional ingredients.
51.21 Canned corn, canned sweet corn, canned sugar corn; quality; label statement of substandard quality.
51.22 Canned corn, canned sweet corn, canned sugar corn where the corn ingredient is in one of the forms known as fritter corn, ground corn, or cream-style corn; fill of container; label statement of substandard fill.
51.30 Canned field corn; identity; label statement of optional ingredients.
51.32 Canned field corn where the corn ingredient is in one of the forms known as fritter field corn, ground field corn, or cream-style field corn; fill of containers; label statement of substandard fill.

CANNED MUSHROOMS

51.503 Canned mushrooms; fill of container; label statement of substandard fill.

CANNED VEGETABLES OTHER THAN THOSE SPECIFICALLY REGULATED

51.990 Canned vegetables other than those specifically regulated; identity; label statement of optional ingredients.

AUTHORITY: §§ 51.1 to 51.990 issued under sec. 701 (a), 52 Stat. 1055; 21 U. S. C. 371 (a). Interpret or apply sec. 401, 52 Stat. 1046, 68 Stat. 54; 21 U. S. C. 241.

CANNED PEAS

§ 51.1 *Identity; label statement of optional ingredients.* (a) Canned peas is the food prepared from one of the following optional pea ingredients:

(1) Shelled, succulent peas (Pisum sativum) of Alaska or other smooth skin varieties.

(2) Shelled, succulent peas (Pisum sativum) of sweet, wrinkled varieties.

(3) Shelled, dried peas (Pisum sativum) of Alaska or other smooth skin varieties.

(4) Shelled, dried peas (Pisum sativum) of sweet, wrinkled varieties.

(b) To one such optional pea ingredient water is added.

(c) The following optional ingredients may be used:

(1) Salt;
(2) Monosodium glutamate;
(3) Sugar;
(4) Dextrose;
(5) Spice;
(6) Flavoring;
(7) Artificial coloring;

and in case optional pea ingredient (1) or (3) is used,

(8) Sodium carbonate, sodium bicarbonate, sodium hydroxide, calcium hydroxide, magnesium hydroxide, magnesium oxide, or magnesium carbonate or any mixture or combination of them in such quantity that the pH of the finished canned peas is not more than 8, as determined by the glass electrode method for the hydrogen ion concentration.

(d) The food may be seasoned with one or more of the following optional seasonings:

(1) Green peppers.
(2) Mint leaves.
(3) Onions.
(4) Garlic.
(5) Horseradish.

(e) The food is sealed in a container and so processed by heat as to prevent spoilage.

(f) (1) The label shall name the optional pea ingredient present by the use of the word or words "Early" or "June" or "Early June," "Sweet" or "Sweet Wrinkled" or "Sugar," "Dried Early" or "Dried June" or "Dried Early June," "Dried Sweet" or "Dried Sweet Wrinkled" or "Dried Sugar."

(2) If spice is present, the label shall bear the word or words "Spiced" or "With Added Spice" or "Spice Added."

(3) If flavoring is present, the label shall bear the words "With Added Flavoring" or "Flavoring Added."

(4) If artificial coloring is present, the label shall state that fact in such manner and form as is provided in § 51.2 (c).

(5) If an optional seasoning ingredient is used, the label shall bear the words "Seasoned with Green Peppers," "Seasoned with Mint Leaves," "Seasoned with Onions," "Seasoned with Garlic," or "Seasoned with Horseradish," as the case may be.

(6) If one or more of the optional ingredients named in paragraph (c) (8) of this section is used, the label shall bear the statement "Traces of ______ Added," the blank to be filled in with the names of the ingredients used; but in lieu of such statement the label may bear the statement "Traces of Alkalis Added."

(7) If monosodium glutamate is used, the label shall bear the statement "Monosodium Glutamate Added" or "With Added Monosodium Glutamate."

(8) Wherever the name "Peas" appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements herein specified, showing the optional ingredients present, shall immediately and conspicuously precede or follow such name without intervening written, printed, or graphic matter, except that the specific varietal name of the peas may so intervene.

§ 51.2 *Quality; label statement of substandard quality.* (a) The standard of quality for canned peas is as follows:

(1) Not more than 4 percent by count of the peas in the container are spotted or otherwise discolored;

(2) Standard canned peas are normally colored, not artificially colored;

(3) The combined weight of pea pods and other harmless extraneous vegetable material is not more than one-half of 1 percent of the drained weight of peas in the container;

(4) The weight of pieces of peas is not more than 10 percent of the drained weight of peas in the container;

(5) The skins of not more than 25 percent by count of the peas in the container are ruptured to a width of 1/16 inch or more;

(6) Not less than 90 percent by count of the peas in the container are crushed by a weight of not more than 907.2 grams (2 pounds); and

(7) The alcohol-insoluble solids of Alaska or other smooth skin varieties of peas in the container, is not more than 23.5 percent, and of sweet, wrinkled varieties, not more than 21 percent.

(b) Canned peas shall be tested by the following methods to determine whether or not they meet the requirements of paragraph (a) of this section:

(1) After determining the fill of the container as prescribed in § 51.3 (a), distribute the contents of the container over the meshes of a circular sieve made with No. 8 woven-wire cloth which complies with the specifications for such cloth set forth on page 3 of "Standard Specifications for Sieves," published October 25, 1938, by United States Department of Commerce, National Bureau of Standards. The diameter of the sieve used is 8 inches if the quantity of the contents of the container is less than 3 pounds, or 12 inches if such quantity is 3 pounds or more. Without shifting the peas, so incline the sieve as to facilitate drainage. Two minutes from the time drainage begins, remove the peas from the sieve and weigh them. Such weight shall be considered to be the drained weight of the peas.

(2) From the drained peas obtained in subparagraph (1) of this paragraph, promptly segregate and weigh the pea pods and other harmless extraneous vegetable material, and the pieces of peas.

(3) From the drained peas obtained in subparagraph (1) of this paragraph, take at random a subdivision of 100 to 150 peas, and count them. Immediately cover these peas with a portion of the liquid obtained in subparagraph (1) of this paragraph, and add the remaining liquid to the drained peas from which the subdivision was taken. Count those peas in the subdivision which are spotted or

otherwise discolored, and also those peas the skins of which are ruptured to a width of 1/16 inch or more.

(4) Immediately after each pea is examined by the method prescribed in subparagraph (3) of this paragraph, test it by removing its skin, placing one of its cotyledons, with flat surface down, on the approximate center of the level, smooth surface of a rigid plate, lowering a horizontal disc to the highest point of the cotyledon, and measuring the height of the cotyledon. The disc is of rigid material and is affixed to a rod held vertically by a support through which the rod can freely move upward or downward. The lower face of the disc is a smooth, plane surface horizontal to the vertical axis of the rod. A device to which weight may be added is affixed to the upper end of the rod. Before lowering the disc to the cotyledon, adjust the combined weight of disc, rod, and device to 100 grams. After measuring the height of the cotyledon, and shifting the plate, if necessary, so that the cotyledon is under the approximate center of the disc, add weight to the device at a uniform, continuous rate of 12 grams per second until the cotyledon is pressed to one-fourth its previously measured height, or until the combined weight of disc, rod, and device is 907.2 grams (2 pounds). A pea so tested shall be considered to be crushed when its cotyledon is pressed to one-fourth its original height.

(5) Drain the liquid from the peas which remained after taking the subdivision as prescribed in subparagraph (3) of this paragraph. Transfer the peas to a pan, and rinse them with a volume of water equal to twice the capacity of the container from which such peas were drained in subparagraph (1) of this paragraph. Immediately drain the peas again by the method prescribed in subparagraph (1) of this paragraph. After the 2 minutes' draining, wipe the moisture from the bottom of the sieve. Comminute the peas thus drained, stir them to a uniform mixture, and weigh 20 grams of such mixture into a 600 cc. beaker. Add 300 cc of 80 percent alcohol (by volume), stir, cover beaker, and bring to a boil. Simmer slowly for 30 minutes. Fit a Buchner funnel with a previously prepared filter paper of such size that its edges extend ½ inch or more up the vertical sides of the funnel. The previous preparation of the filter paper consists of drying it in a flat-bottomed dish for 2 hours at 100° Centigrade, covering the dish with a tight-fitting cover, cooling it in a desiccator, and promptly weighing. After the filter paper is fitted to the funnel, apply suction and transfer the contents of the beaker to the funnel. Do not allow any of the material to run over the edge of the paper. Wash the material on the filter with 80 percent alcohol (by volume) until the washings are clear and colorless. Transfer the filter paper with the material retained thereon to the dish used in preparing the filter paper. Dry the material in a ventilated oven, without covering the dish, for 2 hours at 100° Centigrade. Place the cover on the dish, cool it in a desiccator, and promptly weigh. From this weight, subtract the weight of the dish, cover, and paper, as previously found. The weight in grams thus obtained, multiplied by 5, shall be considered to be the percent of alcohol-insoluble solids.

(c) If the quality of canned peas falls below the standard prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard quality specified in § 10.3 (a) of this chapter, in the manner and form therein specified; but in lieu of such general statement of substandard quality when the quality of canned peas falls below the standard in only one respect, the label may bear the alternative statement "Below Standard in Quality ______ ______," the blank to be filled in with the words specified after the corresponding subparagraph number of paragraph (a) of this section which such canned peas fail to meet, as follows: (1) "Excessive Discolored Peas"; (2) "Artificially Colored"; (3) "Excessive Foreign Material"; (4) "Excessive Broken Peas"; (5) "Excessive Cracked Peas"; (6) "Not Tender"; (7) "Excessively Mealy." Such alternative statement shall immediately and conspicuously precede or follow, without intervening written, printed, or graphic matter, the name "Peas" and any words and statements required or authorized to appear with such name by § 51.1 (c).

§ 51.3 *Fill of container; label statement of substandard fill.* (a) The standard of fill of container for canned peas is a fill such that, when the peas and liquid are removed from the container and returned thereto, the leveled peas (irrespective of the quantity of the liquid), 15 seconds after they are so returned completely fill the container. A container with lid attached by double seam shall be considered to be completely filled when it is filled to the level 3/16 inch vertical distance below the top of the double seam; and a glass container shall be considered to be completely filled when it is filled to the level ½ inch vertical distance below the top of the container.

(b) If canned peas fall below the standard of fill of container prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard fill specified in § 10.2 (b) of this chapter, in the manner and form therein specified.

CANNED BEANS

§ 51.10 *Canned green beans; identity; label statement of optional ingredients.* (a) Canned green beans is the food prepared from stemmed, succulent pods of the green-bean plant, and water. It may be seasoned with salt, monosodium glutamate, sugar, or dextrose, or any two or all of these. The pods are prepared in one or more of the following forms:

(1) Whole pods, including pods which after removal of either or both ends are less than 2¾ inches in length, or transversely cut pods not less than 2¾ inches in length. There may be present such broken pieces of pods as normally occur in the commercial packing of such product.

(2) Pods sliced lengthwise.

(3) Pods cut transversely into pieces less than 2¾ inches in length but not less than ¾ inch in length, with or without shorter end pieces resulting therefrom.

(4) Pieces of pods of which not less than 75 percent by count are less than ¾ inch in length and not more than 1 percent by count are more than 1¼ inches in length.

Any such form is an optional ingredient. Mixtures of two or more optional ingredients may be used. The food is sealed in a container and so processed by heat as to prevent spoilage.

(b) (1) When optional ingredient specified in paragraph (a) (1) of this section is used the label shall bear the word "Whole." If the pods are packed parallel to the sides of the container the word "Whole" shall be preceded or followed by the words "Vertical Pack," except that when the pods are cut at both ends and are of substantially equal lengths, the words "Asparagus Style" may be used in lieu of the words "Vertical Pack."

(2) When optional ingredient specified in paragraph (a) (2) of this section is used the label shall bear the words "Sliced Lengthwise" or "French Style."

(3) When optional ingredient specified in paragraph (a) (3) of this section is used the label shall bear the word "Cut" or "Cuts."

(4) When optional ingredient specified in paragraph (a) (4) of this section is used the label shall bear the words "Short Cut" or "Short Cuts" or "______ Inch Cut" or "______ Inch Cuts," the blank to be filled in with the fraction of an inch which denotes the approximate length of the pieces.

(5) When a mixture of two or more of the optional ingredients specified in paragraphs (a) (1) to (a) (4), inclusive, of this section, is used the label shall bear the statement "Mixture of ______," the blank to be filled in with the combination of the names "Whole," "Sliced Lengthwise," "Cut," or "Cuts," and "Short Cut" or "Short Cuts," designating the optional ingredients present, and arranged in the order of predominance, if any, by weight of such ingredients.

(6) If monosodium glutamate is used, the label shall bear the statement "Monosodium Glutamate Added" or "With Added Monosodium Glutamate."

(c) Wherever the name "Green Beans" appears on the label so conspicuously as to be easily seen under the customary conditions of purchase, the words and statements prescribed by paragraph (b) of this section shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter, except that there may intervene (1) the designation of the length of cut, (2) the varietal name, which may include the word "Stringless," where the beans are in fact stringless, and (3) the description of the green beans as "Stringless," which may also be used between the words "Green" and "Beans," where the beans are in fact stringless.

§ 51.11 *Canned green beans; quality; label statement of substandard quality.*

(a) The standard of quality of canned green beans is as follows:

When tested by the method prescribed in paragraph (b) of this section:

(1) In the case of cut beans (§ 51.10 (a) (3)) and mixtures of two or more of the optional ingredients specified in § 51.10 (a) (1) to (a) (4), inclusive, not more than 60 units per 12 ounces drained weight are less than ½ inch long; *Provided*, That where the number of units per 12 ounces drained weight exceed 240, not more than 25 percent by count of the total units are less than ½ inch long.

(2) The trimmed pods contain not more than 25 percent by weight of seed and pieces of seed.

(3) In case there are present pods or pieces of pods 27/64 inch or more in diameter, there are not more than 12 strings per 12 ounces of drained weight which will support ½ pound for 5 seconds or longer.

(4) The deseeded pods contain not more than 0.15 percent by weight of fibrous material.

(5) There are not more than 8 percent by count of blemished units. A unit is considered blemished when the aggregate blemished area exceeds the area of a circle ⅛ inch in diameter.

(6) There are not more than 6 unstemmed units per 12 ounces of drained weight.

(7) The combined weight of loose seed and pieces of seed is not more than 5 percent of the drained weight. This provision does not apply in case the green-bean ingredient is pods sliced lengthwise (§ 51.10 (a) (2)).

(8) The combined weight of leaves, detached stems, and other extraneous vegetable matter is not more than 0.6 ounce per 60 ounces drained weight.

(b) Canned green beans shall be tested by the following method to determine whether they meet the requirements of paragraph (a) of this section.

(1) Distribute the contents of the container over the meshes of a circular sieve which has been previously weighed. The diameter of the sieve is 8 inches if the quantity of the contents of the container is less than 3 pounds, and 12 inches if such quantity is 3 pounds or more. The bottom of the sieve is woven-wire cloth which complies with the specifications for such cloth set forth under "2380 Micron (No. 8)" in Table I of "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the United States Department of Commerce, National Bureau of Standards. Without shifting the material on the sieve, so incline the sieve as to facilitate drainage. Two minutes from the time drainage begins, weigh the sieve and the drained material. Record, in ounces, the weight so found, less the weight of the sieve, as the drained weight.

(2) Pour the drained material from the sieve into a flat tray and spread it in a layer of fairly uniform thickness. Count the total number of units. For the purpose of this count, loose seed, pieces of seed, loose stems, and extraneous material are not to be included. Divide the number of units by the drained weight recorded in subparagraph (1) of this paragraph and multiply by 12 to obtain the number of units per 12 ounces drained weight.

(3) Examine the drained material in the tray, counting and recording the number of blemished units, number of unstemmed units, and, in case the material consists of the optional ingredient specified in paragraph (a) (3) of this section or a mixture of two or more of the optional ingredients specified in § 51.10 (a) (1) to (4), inclusive, count and record the number of units which are less than ½ inch long. If the number of units per 12 ounces is 240 or less, divide the number of units which are less than ½ inch long by the drained weight recorded in subparagraph (1) of this paragraph and multiply by 12 to obtain the number of such units per 12 ounces drained weight. If the number of units per 12 ounces exceeds 240, divide the number of units less than ½ inch long by the total number of units and multiply by 100 to determine the percentage by count of the total units which are less than ½ inch long.

Divide the number of blemished units by the total number of units in the container and multiply by 100 to obtain the percentage by count of blemished units in the container.

Divide the number of unstemmed units by the drained weight recorded in subparagraph (1) of this paragraph and multiply by 12 to obtain the number of unstemmed units per 12 ounces of drained weight.

(4) Except in the case of pods sliced lengthwise, remove the loose seed and pieces of seed, weigh and record weight and return to tray. Divide the weight of loose seed and pieces of seed by the drained weight recorded in subparagraph (1) of this paragraph and multiply by 100 to obtain the percentage by weight of loose seed and pieces of seed in the drained material.

(5) Remove from the tray the extraneous vegetable material, weigh, record weight, and return to tray.

(6) Remove from the tray one or more representative samples of 3½ to 4 ounces, covering each sample as taken to prevent evaporation. If the tray includes pods or pieces of pods 27/64 inch or more in diameter, weigh and record weight in ounces of each representative sample.

(7) From each representative sample selected in subparagraph (6) of this paragraph discard any loose seed and extraneous vegetable material and detach and discard any attached stems. Except with optional ingredient specified in § 51.10 (a) (2) (pods sliced lengthwise), trim off, as far as the end of the space formerly occupied by the seed, any portion of pods from which seed have become separated. Remove and discard any portions of seed from the trimmings and reserve the trimmings for subparagraph (9) of this paragraph. Weigh and record the weight of the trimmed pods. Deseed the trimmed pods and reserve the deseeded pods for subparagraph (9) of this paragraph. If the original container contained pods 27/64 inch or more in diameter, remove strings from the pods during the deseeding operation. Reserve these strings for testing as prescribed in subparagraph (8) of this paragraph. Collect the seed on a sieve of mesh fine enough to retain them, and so distribute them that any liquid drains away. Weigh the seed, divide by the weight of the trimmed pods, and multiply by 100 to obtain the percentage by weight of seed in the trimmed pods.

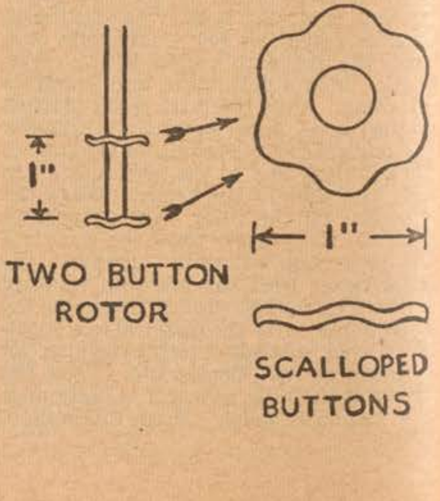
In the case of pods sliced lengthwise, remove seed and pieces of seed and reserve the deseeded pods for use as prescribed in subparagraph (9) of this paragraph.

(8) If strings have been removed for testing, as prescribed in subparagraph (7) of this paragraph, test them as follows:

Fasten clamp, weighted to ½ pound, to one end of the string, grasp the other end with the fingers (a cloth may be used to aid in holding the string), and lift gently. Count the string as tough if it supports the ½-pound weight for at least 5 seconds. If the string breaks before 5 seconds, test such parts into which it breaks as are ½ inch or more in length and if any such part of the string supports the ½-pound weight for at least 5 seconds count the string as tough. Divide the number of tough strings by the weight of the sample recorded in subparagraph (6) of this paragraph and multiply by 12 to obtain the number of tough strings per 12 ounces drained weight.

(9) Combine the deseeded pods with the trimmings reserved in subparagraph (7) of this paragraph, and, if strings were tested as prescribed in subparagraph (8) of this paragraph, add such strings, broken or unbroken. Weigh and record weight of combined material. Transfer to the metal cup of a malted-milk stirrer and mash with a pestle. Wash material adhering to the pestle back into cup with 200 cc. of boiling water. Bring mixture nearly to a boil, add 25 cc. of 50 percent (by weight) sodium hydroxide solution and bring to a boil. (If foaming is excessive, 1 cc. of capryl alcohol may be added.) Boil for 5 minutes, then stir for 5 minutes with a malted-milk stirrer capable of a no-load speed of at least 7200 r. p. m. Use a rotor with two scalloped buttons shaped as shown in the diagram in Exhibit 1.

EXHIBIT 1



Transfer the material from the cup to a previously weighed 30-mesh monel metal screen having a diameter of about 3½ to 4 inches and side walls about 1 inch high, and wash fiber on the screen with a stream of water using a pressure not exceeding a head (vertical distance between upper level of water and outlet of glass tube) of 60 inches, delivered through a glass tube 3 inches long and ⅛ inch inside diameter inserted into a rubber tube of ¼ inch inside diameter. Wash the pulpy portion of the material through the screen and continue washing until the remaining fibrous material, moistened with phenolphthalein solution, does not show any red color after standing 5 minutes. Again wash to remove phenolphthalein. Dry the screen containing the fibrous material for 2 hours at 100° C., cool, weigh, and deduct weight of screen. Divide the weight of fibrous material by the weight of combined deseeded pods, trimmings, and strings and multiply by 100 to obtain the percentage of fibrous material.

(10) If the drained weight recorded in subparagraph (1) of this paragraph was less than 60 ounces, open and examine separately for extraneous material, as directed in subparagraph (5) of this paragraph, additional containers until a total of not less than 60 ounces of drained material is obtained. To determine the combined weight of extraneous vegetable material per 60 ounces of drained weight, total the weights of extraneous vegetable material found in all containers opened, divide this sum by the sum of the drained weights in these containers and multiply by 60.

(c) If the quality of the canned green beans falls below the standard of quality prescribed by paragraph (a) of this section, the label shall bear the general statement of substandard quality specified in § 10.3 (a) of this chapter, in the manner and form therein specified, but in lieu of the words prescribed for the second line inside the rectangle the following words may be used, when the quality of canned green beans falls below the standard in one only of the following respects:

(1) "Excessive Number Very Short Pieces," if the canned green beans fail to meet the requirements of paragraph (a) (1) of this section.

(2) "Excessive Number Blemished Units," if they fail to meet the requirements of paragraph (a) (5) of this section.

(3) "Excessive Number Unstemmed Units," if they fail to meet the requirements of paragraph (a) (6) of this section.

(4) "Excessive Foreign Material," if they fail to meet the requirement of paragraph (a) (8) of this section.

§ 51.15 *Canned wax beans; identity; label statement of optional ingredients.* (a) Canned wax beans conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients prescribed for canned green beans by § 51.10 (a) and (b), except that it is prepared from stemmed, succulent pods of the wax-bean plant.

(b) Wherever the name "Wax Beans" appears on the label so conspicuously as to be easily seen under the customary conditions of purchase, the words and statements prescribed by paragraph (a) of this section shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter, except that there may intervene (1) the designation of the length of cut, (2) the varietal name, which may include the word "Stringless" where the beans are in fact stringless, and (3) the description of the wax beans as "Stringless," which may also be used between the words "Wax" and "Beans," where the beans are in fact stringless.

§ 51.16 *Canned wax beans; quality; label statement of substandard quality.* (a) The standard of quality for canned wax beans is that prescribed for canned green beans by § 51.11 (a) and (b).

(b) If the quality of canned wax beans falls below the standard of quality prescribed by paragraph (a) of this section the label shall bear the statement of substandard quality in the manner and form specified in § 51.11 (c) for canned green beans.

CANNED CORN

§ 51.20 *Canned corn, canned sweet corn, canned sugar corn; identity; label statement of optional ingredients.* (a) Canned corn, canned sweet corn, canned sugar corn is the food consisting of one of the corn ingredients specified in paragraph (b) of this section, with water necessary for proper preparation and processing. It may be seasoned or garnished with one or more of the following optional ingredients:

(1) Salt.

(2) Monosodium glutamate.

(3) Sugar (sucrose).

(4) Pieces of sweet red peppers or sweet green peppers or hot red peppers or hot green peppers or a mixture of any two or more of these.

It is sealed in a container and so processed by heat as to prevent spoilage.

(b) The corn ingredients referred to in paragraph (a) of this section consist of succulent sweet corn of the white or yellow color groups, or mixtures of these, and are as follows:

(1) Cut kernels from which the hulls have not been separated.

(2) Pieces of the inner portion of the corn kernel substantially free from hull.

(3) Ground kernels from which the hulls have not been separated.

(4) A mixture of the form described in subparagraph (1) of this paragraph with one or both of the forms described in subparagraphs (2) and (3) of this paragraph. When necessary to insure smoothness, starch may be added, in a quantity not more than sufficient for that purpose.

(5) Cut and cooked kernels from which most of the moisture has been evaporated.

In preparing each of the foregoing corn ingredients, the tip caps are removed.

(c) (1) The name of the food is: "Corn" or "Sweet Corn" or "Sugar Corn" with the name of the color group used, "White," "Yellow," or "Golden," or with the names of the color groups used, "White and Yellow" or "White and Golden," when the white color group predominates, and "Yellow and White" or "Golden and White," when the yellow color group predominates, and with:

(i) The words "Whole Kernel" or "Whole Grain," when the corn ingredient specified in paragraph (b) (1) of this section is used. When the weight of the liquid in the container, as determined by the method prescribed in § 51.21 (b) (1), is not more than 20 percent of the net weight, and the container is closed under conditions creating a high vacuum in the container, the words "Vacuum Pack" or "Vacuum Packed" also are part of the name.

(ii) The word "Fritter," when the corn ingredient specified in paragraph (b) (2) of this section is used.

(iii) The word "Ground," when the corn ingredient specified in paragraph (b) (3) of this section is used.

(iv) The words "Cream Style," when the corn ingredient specified in paragraph (b) (4) of this section is used.

(v) The word "Evaporated," when the corn ingredient specified in paragraph (b) (5) of this section is used.

(2) The parts of the name as specified in subparagraph (1) of this paragraph may be arranged in any order of precedence. The varietal name of the corn used may intervene between parts of the name of the food. For the purpose of arrangement of the name, the words "Sweet" and "Corn" may be treated as separate parts of the name. When the varietal name immediately precedes or follows the name or intervenes between parts of the name of the food and it accurately designates the color of the corn ingredient, no other designation of the color group need be made.

(d) (1) When the optional seasoning or garnishing ingredient specified in paragraph (a) (4) of this section is used, the label shall bear the words "With __________ ________ peppers," the blanks being filled in with the words "red" or "green" or both, to show the color of peppers used, and "sweet" or "hot" or both, to show the kind of peppers used, as for example "With green sweet peppers" or "With hot red peppers."

(2) If monosodium glutamate is used, the label shall bear the statement "Monosodium Glutamate Added" or "With Added Monosodium Glutamate."

(3) When the optional starch ingredient specified in paragraph (b) (4) of this section is used, the label shall bear the statement "Starch added to insure smoothness."

(e) Wherever the name of the food appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements prescribed by paragraph (d) of this section shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter, except that the varietal name of the corn used may so intervene.

§ 51.21 *Canned corn, canned sweet corn, canned sugar corn; quality; label statement of substandard quality.* (a) The standard of quality for canned corn is as follows:

(1) When tested by the method prescribed in paragraph (b) of this section, canned corn in which the corn ingredient is whole-kernel corn (§ 51.20 (b) (1)) or evaporated corn (§ 51.20 (b) (5)):

(i) Contains not more than one brown or black discolored kernel or piece of kernel for each 2 ounces of drained weight;

(ii) Contains not more than 1 cubic centimeter of pieces of cob for each 14 ounces of drained weight;

(iii) Contains not more than 1 square inch of husk for each 14 ounces of drained weight; and

(iv) Contains not more than 7 inches of silk for each 1 ounce of drained weight.

(2) When tested by the method prescribed in paragraph (c) of this section, canned corn in which the corn ingredient is fritter corn (§ 51.20 (b) (2)), ground corn (§ 51.20 (b) (3)), or cream-style corn (§ 51.20 (b) (4)):

(i) Contains not more than one brown or black discolored kernel or piece of kernel for each 2 ounces of net weight;

(ii) Contains not more than 1 cubic centimeter of pieces of cob for each 20 ounces of net weight;

(iii) Contains not more than 1 square inch of husk for each 20 ounces of net weight;

(iv) Contains not more than 6 inches of silk for each 1 ounce of net weight; and

(v) Has a consistency such that the average diameter of the approximately circular area over which the prescribed sample spreads does not exceed 12 inches, except that, in the case of cream-style corn the washed drained material of which contains more than 20 percent of alcohol-insoluble solids, the average diameter of the approximately circular area over which the prescribed sample spreads does not exceed 10 inches.

(3) (i) The weight of the alcohol-insoluble solids of whole-kernel corn (§ 51.20 (b) (1)) does not exceed 27 percent of the drained weight, when tested by the method prescribed in paragraph (b) of this section.

(ii) The weight of the alcohol-insoluble solids of the washed drained material of cream-style corn (§ 51.20 (b) (4)) does not exceed 27 percent of the weight of such material, when tested by the method prescribed in paragraph (c) of this section.

(b) The method referred to in paragraph (a) of this section for testing whole-kernel corn (§ 51.20 (b) (1)) and evaporated corn (§ 51.20 (b) (5)) is as follows:

(1) Determine the gross weight of the container. Open and distribute the contents of the container over the meshes of an 8-mesh circular sieve which has previously been weighed. The diameter of the sieve is 8 inches if the quantity of the contents of the container is less than 3 pounds, and 12 inches if such quantity is 3 pounds or more. The bottom of the sieve is woven-wire cloth which complies with the specifications for such cloth set forth under "2380 Micron (No. 8)" in Table I of "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the U. S. Department of Commerce, National Bureau of Standards. Without shifting the material on the sieve, so incline the sieve as to facilitate drainage. Two minutes from the time drainage begins, weigh the sieve and the drained material. Record, in ounces, the weight so found, less the weight of the sieve, as the drained weight. Dry and weigh the empty container and subtract this weight from the gross weight to obtain the net weight. Calculate the percent of drained liquid in the net weight.

(2) Pour the drained material from the sieve into a flat tray and spread it in a layer of fairly uniform thickness. Count, but do not remove, the brown or black discolored kernels or pieces of kernel and calculate the number per 2 ounces of drained material. Remove pieces of silk more than ½-inch long, husk, cob, and any pieces of material other than corn. Measure the aggregate length of such pieces of silk and calculate the length of silk per 1 ounce of drained weight. Spread the husk flat, measure its aggregate area, and calculate the area of husk per 14 ounces of drained weight. Place all pieces of cob under a measured amount of water in a cylinder which is so graduated that the volume can be measured to 0.1 cubic centimeter. Take the increase in volume as the aggregate volume of the cob and calculate the volume of cob per 14 ounces of drained weight.

(3) If the corn is whole kernel (§ 51.20 (b) (1)), comminute a representative 100-gram sample of the drained corn from which the silk, husk, cob, and other material which is not corn (i. e., peppers) have been removed. An equal amount of water is used to facilitate this operation. Weigh to nearest 0.01 gram a portion of the comminuted material equivalent to approximately 10 grams of the drained corn into a 600-cubic centimeter beaker. Add 300 cubic centimeters of 80-percent alcohol (by volume), stir, cover beaker, and bring to a boil. Simmer slowly for 30 minutes. Fit a Buchner funnel with a previously prepared filter paper of such size that its edges extend ½ inch or more up the vertical sides of the funnel. The previous preparation of the filter paper consists of drying it in a flat-bottomed dish for 2 hours at 100° C., covering the dish with a tight-fitting cover, cooling it in a desiccator, and promptly weighing to the nearest 0.001 gram. After the filter paper is fitted to the funnel, apply suction and transfer the contents of the beaker to the funnel. Do not allow any of the material to run over the edge of the paper. Wash the material on the filter with 80-percent alcohol (by volume) until the washings are clear and colorless. Transfer the filter paper with the material retained thereon to the dish used in preparing the filter paper. Dry the material in a ventilated oven, without covering the dish, for 2 hours at 100° C. Place the cover on the dish, cool it in a desiccator, and promptly weigh to the nearest 0.001 gram. From this weight subtract the weight of the dish, cover, and paper as previously found. Calculate the remainder to percentage.

(c) The method referred to in paragraph (a) of this section for testing fritter corn (§ 51.20 (b) (2)), ground corn (§ 51.20 (b) (3)), and cream-style corn (§ 51.20 (b) (4)) is as follows:

(1) Allow the container to stand at least 24 hours at a temperature of 68° F. to 85° F. Determine the gross weight, open, transfer the contents into a pan, and mix thoroughly in such a manner as not to incorporate air bubbles. (If the net contents of a single container is less than 18 ounces, determine the gross weight, open, and mix the contents of the least number of containers necessary to obtain 18 ounces.) Fill level full a hollow, truncated cone so placed on a polished horizontal plate as to prevent leakage. The cone has an inside bottom diameter of 3 inches, inside top diameter of 2 inches, and height of $4\frac{27}{32}$ inches. As soon as the cone is filled, lift it vertically. Determine the average of the longest and shortest diameters of the approximately circular area on the plate covered by the sample 30 seconds after lifting the cone. Dry and weigh each empty container and subtract the weight so found from the gross weight to obtain the net weight.

(2) Transfer the material from the plate, cone, and pan onto an 8-mesh sieve as prescribed in paragraph (b) (1) of this section. The diameter of the sieve is 8 inches if the quantity of the contents of the container is less than 3 pounds, and 12 inches if such quantity is 3 pounds or more. Set the sieve in a pan. Add enough water to bring the level within ⅜ inch to ¼ inch of the top of the sieve. Gently wash the material on the sieve by combined up-and-down and circular motion for 30 seconds. Repeat washing with a second portion of water. Remove sieve from pan, incline to facilitate drainage, and drain for 2 minutes.

(3) From the material remaining on the 8-mesh sieve, count, but do not remove, the brown or black discolored kernels or pieces of kernel and calculate the number per 2 ounces of net weight. Remove pieces of silk more than ½-inch long, husk, cob, and other material which is not corn (i. e., peppers). Measure aggregate length of such pieces of silk and calculate the length per ounce of net weight. Spread the husk flat and measure its aggregate area and calculate the area per 20 ounces of net weight. Place all pieces of cob under a measured amount of water in a cylinder which is so graduated that the volume may be measured to 0.1 cubic centimeter. Take the increase in volume as the aggregate volume of the cob and calculate the volume of cob per 20 ounces of net weight. If the corn is cream-style corn (§ 51.20 (b) (4)), take a representative 100-gram sample of the material remaining on the 8-mesh sieve (if such material weighs less than 100 grams take all of it) and determine the alcohol-insoluble solids as prescribed in paragraph (b) (3) of this section for whole-kernel corn.

(d) If the quality of canned corn falls below the standard prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard quality specified in § 10.2 (a) of this chapter, in the manner and form therein specified; however, if the quality of the canned corn falls below standard with respect to only one of the factors of quality specified by subdivisions (i) to (iv) of paragraph (a) (1) of this section, or by subdivisions (i) to (v) of paragraph (a) (2) of this section, there may be substituted for the second line of such general statement of substandard quality, "Good Food—Not High Grade," a new line as specified after the corresponding subdivision designation of paragraph (a) of this section which the canned corn fails to meet:

(1) (i) or (2) (i) "Excessive discolored kernels."

(1) (ii) or (2) (ii) "Excessive cob."

(1) (iii) or (2) (iii) "Excessive husk."

(1) (iv) or (2) (iv) "Excessive silk."

(2) (v) "Excessively liquid."

§ 51.22 *Canned corn, canned sweet corn, canned sugar corn where the corn ingredient is in one of the forms known as fritter corn, ground corn, or cream-style corn; fill of container; label statement of substandard fill.* (a) The standard of fill of container for canned corn where the corn ingredient is in one of the forms known as fritter corn (§ 51.20 (b) (2)), ground corn (§ 51.20 (b) (3)), or cream-style corn (§ 51.20 (b) (4)) is a fill of not less than 90 percent of the total capacity of the container, as determined by the general method for fill of containers prescribed in § 10.1 (b) of this chapter.

(b) If canned fritter corn, canned ground corn, or canned cream-style corn falls below the standard of fill of container prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard fill specified in § 10.2 (b) of this chapter, in the manner and form therein specified.

§ 51.30 *Canned field corn; identity; label statement of optional ingredients.* (a) Canned field corn conforms to the definition and standard of identity, and is subject to the requirements for label statement of optional ingredients, prescribed for canned corn by § 51.20, except that the corn ingredient consists of succulent field corn or a mixture of succulent field corn and succulent sweet corn.

(b) The name of the food conforms to the name specified in § 51.20 (c), except that the words "Corn," "Sweet Corn," and "Sugar Corn" are replaced by the words "Field Corn," and the term "Golden Field Corn" is not used.

§ 51.32 *Canned field corn where the corn ingredient is in one of the forms known as fritter field corn, ground field corn, or cream-style field corn; fill of container; label statement of substandard fill.* Each of the foods canned fritter field corn, canned ground field corn, and canned cream-style field corn conforms to the standard of fill of container and label statement of substandard fill prescribed for canned fritter corn, canned ground corn, and canned cream-style corn by § 51.22 (a) and (b).

CANNED MUSHROOMS

§ 51.503 *Canned mushrooms; fill of container; label statement of substandard fill.* The standard of fill of container for canned mushrooms is a fill such that:

(a) The weight of drained mushrooms in a container the dimensions of which are specified in the following table is not less than the weight of drained mushrooms prescribed in such table for such container:

Trade designation	Over-all dimensions sealed can		Weight of drained mushrooms
	Diameter	Height	
	Inches	*Inches*	*Ounces (avoirdupois)*
202 x 204	2⅛	2¼	2
211 x 212	2 11/16	2¾	4
300 x 400	3	4	8
307 x 510	3 7/16	5⅝	16
603 x 700	6 3/16	7	68

(b) The drained weight of mushrooms in containers of a size not specified in paragraph (a) of this section is not less than 56 percent of the water capacity of the container, if such water capacity is less than 11.0 ounces avoirdupois; not less than 59 percent of the water capacity of the container, if such water capacity is 11.0 ounces or more but less than 25 ounces avoirdupois; and not less than 62 percent of the water capacity of the container, if such water capacity is 25 ounces avoirdupois or more.

(c) Water capacity of containers is determined by the general method provided in § 10.2 of this chapter.

(d) Drained weight is determined by the following method: Tilt the opened container so as to distribute the contents evenly over the meshes of a circular sieve which has been previously weighed. The diameter of the sieve is 8 inches if the quantity of contents of the container is less than 3 pounds, and 12 inches if such quantity is 3 pounds or more. The bottom of the sieve is woven-wire cloth which complies with the specifications for such cloth set forth under "2380 Micron (No. 8)" in table I of "Standard Specifications for Sieves," published March 1, 1940, in L. C. 584 of the U. S. Department of Commerce, National Bureau of Standards. Without shifting the material on the sieve, so incline the sieve as to facilitate drainage. Two minutes after drainage begins, weigh the sieve and drained mushrooms. The weight so found, less the weight of the sieve, shall be considered to be the weight of drained mushrooms.

(e) If canned mushrooms fall below the applicable standard of fill of container prescribed in paragraph (a) or (b) of this section, the label shall bear the general statement of substandard fill specified in § 10.3 (b) of this chapter, in the manner and form therein specified.

CANNED VEGETABLES OTHER THAN THOSE SPECIFICALLY REGULATED

§ 51.990 *Canned vegetables other than those specifically regulated; identity; label statement of optional ingredients.* (a) The canned vegetables for which definitions and standards of identity are prescribed by this section are those named in column I of the table set forth in paragraph (b) of this section. The vegetable ingredient in each such canned vegetable is obtained by proper preparation from the succulent vegetable prescribed in column II of such table. If two or more forms of such ingredient are designated in column III of such table, the vegetable in each such form is an optional ingredient.

(b) The table referred to in paragraph (a) of this section is as follows:

I Name or synonym of canned vegetable	II Source	III Optional forms of vegetable ingredient
Artichokes	Flower buds of the artichoke plant	Whole; half or halves or halved; whole hearts; halved hearts; quartered hearts.
Asparagus	Edible portions of sprouts of the asparagus plant, as follows:	
	Three and three-quarter inches or more of upper end.	Stalks or spears.
	Three and three-quarter inches or more of peeled upper end.	Peeled stalks or peeled spears.
	Not less than two and three-quarter inches but less than three and three-quarter inches of upper end.	Tips.
	Less than two and three-quarter inches of upper end.	Points.
	Sprouts cut in pieces	Cut stalks or cut spears.
	Sprouts from which the tip has been removed, cut in pieces.	Bottom cuts or cuts—tips removed.
Bean sprouts	Sprouts of the Mung bean.	
Shelled beans	Seed shelled from green or wax bean pods, with or without snaps (pieces of immature unshelled pods).	
Lima beans or butter beans	Seed shelled from the pods of the lima bean plant.	
Beets	Root of the beet plant	Whole; slices or sliced; quarters or quartered; dice or diced; cut; shoestring or French style or julienne.
Beet greens	Leaves, or leaves and immature root, of the beet plant.	
Broccoli	Heads of the broccoli plant.	
Brussels sprouts	Sprouts of the brussels sprouts plant.	
Cabbage	Cut pieces of the heads of the cabbage plant.	
Carrots	Root of the carrot plant	Do.
Cauliflower	Cut pieces of the head of the cauliflower plant.	
Celery	Stalks of the celery plant	Cut; hearts.
Collards	Leaves of the collard plant.	
Dandelion greens	Leaves of the dandelion plant	
Kale	Leaves of the kale plant.	
Mushrooms	Cap and stem of the mushroom	Buttons; whole; slices or sliced; pieces and stems.
Mustard greens	Leaves of the mustard plant	
Okra	Pods of the okra plant	Whole; cut.
Onions	Bulb of the onion plant	Do.

I Name or synonym of canned vegetable	II Source	III Optional forms of vegetable ingredient
Parsnips	Root of the parsnip plant	Whole; quarters or quartered; slices or sliced; cut; shoestring or French style or julienne.
Black-eye peas or black-eyed peas.	Seed shelled from pods of the black-eye pea plant, with or without snaps (pieces of immature unshelled pods).	
Field peas	Seed shelled from pods of the field pea plant (other than the black-eye pea plant), with or without snaps (pieces of immature unshelled pods).	
Green sweet peppers	Green pods of the sweet pepper plant	Whole; halves or halved; pieces.
Red sweet peppers	Red-ripe pods of the sweet pepper plant	Do.
Pimientos or pimentos	Red-ripe pods of the pimiento, or pimento, pepper plant.	Do.
Potatoes	Tuber of the potato plant	Whole; slices or sliced; dice or diced; pieces; shoestring or French style or julienne.
Sweetpotatoes	Tuber of the sweetpotato plant	Whole; pieces; mashed.
Rutabagas	Root of the rutabaga plant	Whole; quarters or quartered; slices or sliced; dice or diced; cut.
Salsify	Root of the salisfy plant.	
Spinach	Leaves of the spinach plant.	
Swiss chard	Leaves of the Swiss chard plant.	
Truffles	Fruit of the truffle.	
Turnip greens	Leaves of the turnip plant.	
Turnips	Root of the turnip plant	Do.

(c) To the vegetable ingredient water is added; except that pimientos may be canned with or without added water, and sweet potatoes in mashed form are canned without added water, and asparagus may be canned with added water, asparagus juice, or a mixture of both. For the purposes of this section, asparagus juice is the clear, unfermented liquid expressed from the washed and heated sprouts or parts of sprouts of the asparagus plant; mixtures of asparagus juice and water are considered to be water when such mixtures are used as a packing medium for canned asparagus. In the case of artichokes, citric acid or a vinegar is added in such quantity as to reduce the pH of the finished canned vegetable to 4.5 or below. The following optional ingredients, in the case of the vegetables specified, may be added:

(1) Citric acid or a vinegar, in the cases of all vegetables (except artichokes, in which such ingredient is prescribed, and except canned mushrooms, in which no such ingredient is permitted), in a quantity not more than sufficient to permit effective processing by heat without discoloration or other impairment of the article.

(2) An edible vegetable oil, in the cases of artichokes and pimientos.

(3) In the case of potatoes, purified calcium chloride, calcium sulfate, calcium citrate, monocalcium phosphate, or any mixture of two or more such calcium salts, in a quantity reasonably necessary to firm the potatoes, but in no case in a quantity such that the calcium contained in any such calcium salt or mixture is more than 0.051 percent of the weight of the finished food.

(4) Snaps, in the cases of shelled beans, black-eyed peas, and field peas.

(5) Salt may be added to any of the canned vegetables in this section, in a quantity sufficient to season the food.

(6) In the cases of all vegetables (except canned mushrooms) one or more of the following optional seasoning ingredients may be added in a quantity sufficient to season the food:

(i) A vinegar.

(ii) Spice.

(iii) Refined sugar (sucrose).

(iv) Refined corn sugar (dextrose).

(7) In the case of canned mushrooms, ascorbic acid (vitamin C) may be added in a quantity not to exceed 37.5 milligrams for each ounce of drained weight of mushrooms.

(8) In the cases of all vegetables, monosodium glutamate may be added in a quantity sufficient to season the food. The food is sealed in a container, and so processed by heat as to prevent spoilage.

(d) The name of each canned vegetable for which a definition and standard of identity is prescribed by this section is the name of any synonym thereof whereby such vegetable is designated in column I of the table in paragraph (b) of this section.

(e) If two or more forms of the vegetable are specified in column III of the table in paragraph (b) of this section, the label shall bear the specified word or words, or in case synonyms are so specified, one of such synonyms, showing the form of the vegetable ingredient present.

(f) (1) If the optional ingredient specified in paragraph (c) (2) of this section is present, the label shall bear the statement "____________ Oil Added" or "With Added ____________ Oil," the blank being filled in with the common or usual name of the oil.

(2) If the optional ingredient specified in paragraph (c) (3) of this section is present, the label shall bear the statement "Trace of ____________ Added" or "With Added Trace of ____________," the blank being filled in with the words "Calcium Salt" or "Calcium Salts," as the case may be, or with the name or names of the particular calcium salt or salts added.

(3) If the optional ingredient specified in paragraph (c) (4) of this section is present, the label shall bear the statement "With Snaps."

(4) If optional seasoning ingredient of paragraph (c) (6) (i) of this section is present, the label shall bear the statement "Seasoned with Vinegar" or "Seasoned with ____________ Vinegar," the blank being filled in with the common or usual name of the vinegar.

(5) If optional seasoning ingredient of paragraph (c) (6) (ii) of this section is present, the label shall bear the statement "Spice Added" or "With Added Spice."

(6) If a vinegar, spice, and vegetable oil, or any two of these are present, the label may bear, in lieu of the statements prescribed in this section, showing the presence of such ingredients, a combination of such statements, as for example, "With Added Cider Vinegar, Spice, and Olive Oil."

(7) If asparagus juice is used as a packing medium in canned asparagus, the label shall bear the statement "Packed in Asparagus Juice."

(8) If monosodium glutamate is used, the label shall bear the statement "Monosodium Glutamate Added" or "With Added Monosodium Glutamate."

(g) Wherever the name of the vegetable appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the words and statements specified in paragraphs (e) and (f) of this section shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter, except that the varietal name of the vegetable may so intervene.

PART 53—TOMATO PRODUCTS; DEFINITIONS AND STANDARDS OF IDENTITY; QUALITY; AND FILL OF CONTAINER

Sec.
53.1 Tomato juice; identity.
53.5 Yellow tomato juice; identity.
53.10 Catsup, ketchup, catchup; identity; label statement of optional ingredients.
53.20 Tomato puree, tomato pulp; identity; label statement of optional ingredients.
53.30 Tomato paste; identity; label statement of optional ingredients.
53.40 Canned tomatoes; identity; label statement of optional ingredients.
53.41 Canned tomatoes; quality; label statement of substandard quality.
53.42 Canned tomatoes; fill of container; label statement of substandard fill.

AUTHORITY: §§ 53.1 to 53.42 issued under sec. 701 (a), 52 Stat. 1055; 21 U. S. C. 371 (a). Interpret or apply sec. 401, 52 Stat. 1046, 68 Stat. 54; 21 U. S. C. 341.

§ 53.1 *Tomato juice; identity.* Tomato juice is the unconcentrated liquid extracted from mature tomatoes of red or reddish varieties, with or without scalding followed by draining. In the extraction of such liquid, heat may be applied by any method which does not add water thereto. Such liquid is strained free from skins, seeds, and other coarse or hard substances, but carries finely divided insoluble solids from the flesh of the tomato. Such liquid may be homogenized, and may be seasoned with salt. When sealed in a container it is so processed by heat, before or after sealing, as to prevent spoilage.

§ 53.5 *Yellow tomato juice; identity.* Yellow tomato juice is the unconcentrated liquid extracted from mature tomatoes of yellow varieties. It conforms, in all other respects, to the definition and standard of identity for tomato juice prescribed in § 53.1.

§ 53.10 *Catsup, ketchup, catchup; identity; label statement of optional ingredients.* (a) Catsup, ketchup, catchup, is the food prepared from one or any combination of two or all of the following optional ingredients:

(1) The liquid obtained from mature tomatoes of red or reddish varieties.

(2) The liquid obtained from the residue from preparing such tomatoes for canning, consisting of peelings and cores with or without such tomatoes or pieces thereof.

(3) The liquid obtained from the residue from partial extraction of juice from such tomatoes.

Such liquid is obtained by so straining such tomatoes or residue, with or without heating, as to exclude skins, seeds, and other coarse or hard substances. It is concentrated and seasoned with salt, a vinegar or vinegars, spices or flavorings or both, and onions or garlic or both and is sweetened with sugar or a mixture of sugar and dextrose or a mixture of sugar (or sugar and dextrose) with corn sirup or dried corn sirup or both or with glucose sirup or dried glucose sirup or both, in such quantity that the weight of the solids of the corn sirup or dried corn sirup or both, or glucose sirup or dried glucose sirup or both, is not more than one-third of the weight of the solids of such mixture. When sealed in a container it is so processed by heat, before or after sealing, as to prevent spoilage.

(b) (1) For the purposes of this section, the term "corn sirup" means refined corn sirup (including dried corn sirup) the solids of which contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose.

(2) The term "glucose sirup" means a clarified, concentrated, aqueous solution of the products obtained by the incomplete hydrolysis of any edible starch. The solids of glucose sirup contain not less than 40 percent by weight of reducing sugars calculated as anhydrous dextrose. "Dried glucose sirup" means the product obtained by drying "glucose sirup."

(c) When optional ingredient specified in paragraph (a) (2) of this section, is present, in whole or in part, the label shall bear the statement "Made From ______" (or "Made in Part From ______," as the case may be) "Residual Tomato Material from Canning." When optional ingredient specified in paragraph (a) (3) of this section is present, in whole or in part, the label shall bear the statement "Made From ______" (or "Made in Part From ______," as the case may be) "Residual Tomato Material from Partial Extraction of Juice." If both such ingredients are present, such statements may be combined in the statement "Made From ______" (or "Made in Part From ______," as the case may be) "Residual Tomato Material from Canning and from Partial Extraction of Juice." Wherever the name "Catsup," "Ketchup" or "Catchup" appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement or statements specified in this paragraph showing the optional ingredients present shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 53.20 *Tomato puree, tomato pulp; identity; label statement of optional ingredients.* (a) Tomato puree, tomato pulp, is the food prepared from one or any combination of two or all of the following optional ingredients:

(1) The liquid obtained from mature tomatoes of red or reddish varieties.

(2) The liquid obtained from the residue from preparing such tomatoes for canning, consisting of peelings and cores with or without such tomatoes or pieces thereof.

(3) The liquid obtained from the residue from partial extraction of juice from such tomatoes.

Such liquid is obtained by so straining such tomatoes or residue, with or without heating, as to exclude skins, seeds, and other coarse or hard substances. It is concentrated, and may be seasoned with salt. When sealed in a container it is so processed by heat, before or after sealing, as to prevent spoilage. It contains not less than 8.37 percent, but less than 25.00 percent, of salt-free tomato solids, as determined by the following method: Determine total solids by the method prescribed on page 499 [Ed. note, 8th edition, 1955, p. 570, sec. 30.2], under "Total Solids—Tentative," and sodium chloride by the method prescribed on page 500 [Ed. note, 8th edition, 1955, p. 571, sec. 30.8. Title changed to "Sodium Chloride Method I—Official."], under "Sodium Chloride—Official," of "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fourth Edition, 1935. Subtract the percent of sodium chloride found from the percent of total solids found; the difference shall be considered to be the percent of salt-free tomato solids.

(b) When optional ingredient specified in paragraph (a) (2) of this section is present, in whole or in part, the label shall bear the statement "Made From ______" (or "Made in Part From ______," as the case may be) "Residual Tomato Material From Canning." When optional ingredient specified in paragraph (a) (3) of this section is present, in whole or in part, the label shall bear the statement "Made From ______" (or "Made in Part From ______," as the case may be) "Residual Tomato Material From Partial Extraction of Juice." If both such ingredients are present, such statements may be combined in the statement "Made From ______" (or "Made in Part From ______," as the case may be) "Residual Tomato Material from Canning and from Partial Extraction of Juice." Wherever the name "Tomato Puree" or "Tomato Pulp" appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement or statements specified in this section, showing the optional ingredients present shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 53.30 *Tomato paste; identity; label statement of optional ingredients.* (a) Tomato paste is the food prepared from one or any combination of two or all of the following optional ingredients:

(1) The liquid obtained from mature tomatoes of red or reddish varieties.

(2) The liquid obtained from the residue from preparing such tomatoes for canning, consisting of peelings and cores with or without such tomatoes or pieces thereof.

(3) The liquid obtained from the residue from partial extraction of juice from such tomatoes.

Such liquid is obtained by so straining such tomatoes or residue, with or without heating, as to exclude skins, seeds, and other coarse or hard substances. It is concentrated, and may be seasoned with one or more of the optional ingredients:

(4) Salt.

(5) Spice.

(6) Flavoring.

It may contain, in such quantity as neutralizes a part of the tomato acids, the optional ingredient:

(7) Baking soda.

When sealed in a container it is so processed by heat, before or after sealing, as to prevent spoilage. It contains not less than 25.00 percent of salt-free tomato solids, as determined by the following method: Determine total solids by the method prescribed on page 499 [Ed. note, 8th edition, 1955, p. 570, sec. 30.2], under "Total Solids—Tentative," and sodium chloride by the method prescribed on page 500 [Ed. note, 8th edition, 1955, p. 571, sec. 30.8], under "Sodium Chloride—Official," of "Official and Tentative Methods of Analysis of the Association of Official Agricultural Chemists," Fourth Edition, 1935. Subtract the percent of sodium chloride found from the percent of total solids found; the difference shall be considered to be the percent of salt-free tomato solids.

(b) When optional ingredient specified in paragraph (a) (2) of this section is present, in whole or in part, the label shall bear the statement "Made From ______" (or "Made in Part From ______," as the case may be) "Residual Tomato Material From Canning." When optional ingredient specified in paragraph (a) (3) of this section is present, in whole or in part, the label shall bear the statement "Made From ______," (or "Made in Part From ______," as the case may be) "Residual Tomato Material From Partial Extraction of Juice." If both such ingredients are present, such statements may be combined in the statement "Made From ______" (or "Made in Part From ______," as the case may be) "Residual Tomato Material From Canning and From Partial Extraction of Juice." When optional ingredient specified in paragraph (a) (5) or (6) of this section is present the label shall bear the statement or statements, "Spice Added" or "With Added Spice," "Flavoring Added" or "With Added Flavoring," as the case may be. When optional ingredient specified in paragraph (a) (7) of this section is present, the label shall bear the statement "Baking Soda Added." If two or all of the optional ingredients specified in paragraph (a) (5), (6), and (7), of this section are present, such statements may be combined, as for example, "Spice, Flavoring, and Baking Soda Added." In lieu of the word "Spice" or "Flavoring" in such statement or statements, the common or usual name of such spice or flavoring may be used.

(c) Wherever the name "Tomato Paste" appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement or statements specified in this section, showing the optional ingredients present shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 53.40 *Canned tomatoes; identity; label statement of optional ingredients.* (a) Canned tomatoes are mature tomatoes of red or reddish varieties which are peeled and cored and to which may be added one or more of the following optional ingredients:

(1) The liquid draining from such tomatoes during or after peeling and coring.

(2) The liquid strained from the residue from preparing such tomatoes for canning, consisting of peelings and cores with or without such tomatoes or pieces thereof.

(3) The liquid strained from mature tomatoes of such varieties.

(4) Purified calcium chloride, calcium sulfate, calcium citrate, monocalcium phosphate, or any two or more of these calcium salts, in a quantity reasonably necessary to firm the tomatoes, but in no case such that the amount of the calcium contained in such salts is more than 0.026 percent of the weight of the finished canned tomatoes.

It may be seasoned with one or more of the optional ingredients:

(5) Salt.

(6) Spices.

(7) Flavoring.

It is sealed in a container and so processed by heat as to prevent spoilage.

(b) When optional ingredient specified in paragraph (a) (2) of this section is present, the label shall bear the statement "With Added Strained Residual Tomato Material From Preparation for Canning." When one or more of the optional ingredients specified in paragraph (a) (4) of this section is present the label shall bear the statement "Trace of ----- Added" or "With Added Trace of ----," the blank being filled in with the words "Calcium Salt" or "Calcium Salts" as the case may be or with the name or names of the particular calcium salt or salts added. When optional ingredient specified in paragraph (a) (6) or (7) of this section is present, the label shall bear the statement or statements "Spice Added" or "With Added Spice," "Flavoring Added" or "With Added Flavoring," as the case may be. If two or more of optional ingredients specified in paragraph (a) (2), (6), and (7) of this section are present, such statements may be combined, as for example, "With Added Strained Residual Tomato Material from Preparation for Canning, Spice, and Flavoring." In lieu of the word "Spice" or "Flavoring" in such statement or statements, the common or usual name of such spice or flavoring may be used. Wherever the name "Tomatoes" appears on the label so conspicuously as to be easily seen under customary conditions of purchase, the statement or statements herein specified showing the optional ingredients present shall immediately and conspicuously precede or follow such name, without intervening written, printed, or graphic matter.

§ 53.41 *Canned tomatoes; quality; label statement of substandard quality.* (a) The standard of quality for canned tomatoes is as follows:

(1) The drained weight, as determined by the method prescribed in paragraph (b) (1) of this section, is not less than 50 percent of the weight of water required to fill the container, as determined by the general method for water capacity of containers prescribed in § 10.2 (a) of this chapter;

(2) The strength and redness of color as determined by the method prescribed in paragraph (b) (2) of this section, is not less than that of the blended color of any combination of the color discs described in such method, in which one-third the area of disc 1, and not more than one-third the area of disc 2, is exposed;

(3) Peel, per pound of canned tomatoes in the container, covers an area of not more than 1 square inch; and

(4) Blemishes, per pound of canned tomatoes in the container, cover an area of not more than one-fourth square inch.

(b) Canned tomatoes shall be tested by the following method to determine whether or not they meet the requirements of paragraph (a) (1) and (2) of this section:

(1) Remove lid from container, but in the case of a container with lid attached by double seam, do not remove or alter the height of the double seam. Tilt the opened container so as to distribute the contents over the meshes of a circular sieve which has previously been weighed. The diameter of the sieve used is 8 inches if the quantity of the contents of the container is less than 3 pounds, or 12 inches if such quantity is 3 pounds or more. The meshes of such sieve are made by so weaving wire of 0.054-inch diameter as to form square openings 0.446 inch by 0.446 inch. Without shifting the tomatoes, so incline the sieve as to facilitate drainage of the liquid. Two minutes from the time drainage begins, weigh the sieve and drained tomatoes. The weight so found, less the weight of the sieve, shall be considered to be the drained weight.

(2) Remove from the sieve the drained tomatoes obtained in subparagraph (1) of this paragraph. Cut out and segregate successively those portions of least redness until 50 percent of the drained weight, as determined under subparagraph (1) of this paragraph, has been so segregated. Comminute the segregated portions to a uniform mixture without removing or breaking the seeds. Fill the mixture into a black container to a depth of at least 1 inch. Free the mixture from air bubbles, and skim off or press below the surface all visible seeds. Compare the color of the mixture, in full diffused daylight or its equivalent, with the blended color of combinations of the following concentric Munsell color discs of equal diameter, or the color equivalents of such discs:

(i) Red—Munsell 5 R 2.6/13 (glossy finish).

(ii) Yellow—Munsell 2.5 YR 5/12 (glossy finish).

(iii) Black—Munsell N 1/ (glossy finish).

(iv) Grey—Munsell N 4 (mat finish).

(c) If the quality of canned tomatoes falls below the standard prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard quality specified in § 10.2 (a) of this chapter in the manner and form therein specified; but in lieu of such general statement of substandard quality, the label may bear the alternative statement "Below Standard in Quality ------"; the blank to be filled in with the words specified after the corresponding number of each subparagraph of paragraph (a) of this section which such canned tomatoes fail to meet, as follows: (1) "Excessively Broken Up"; (2) "Poor Color"; (3) "Excessive Peel"; (4) "Excessive Blemishes." If such canned tomatoes fail to meet both (3) and (4), the words "Excessive Peel and Blemishes" may be used instead of the words specified after the corresponding numbers of such clauses. Such alternative statement shall immediately and conspicuously precede or follow, without intervening written, printed, or graphic matter, the name "Tomatoes" and any statements required or authorized to appear with such name by § 53.40 (b).

§ 53.42 *Canned tomatoes, fill of container; label statement of substandard fill.* (a) The standard of fill of container for canned tomatoes is a fill of not less than 90 percent of the total capacity of the container, as determined by the general method for fill of containers prescribed in § 10.2 (b) of this chapter.

(b) If canned tomatoes fall below the standard of fill of container prescribed in paragraph (a) of this section, the label shall bear the general statement of substandard fill specified in § 10.3 (b) of this chapter, in the manner and form therein specified.

PART 85—SEAFOOD INSPECTION

Subpart A—Inspection of Processed Shrimp

Sec.
85.1 Application for inspection service.
85.2 Granting or refusing inspection service; cancellation of application.
85.3 Inspection periods.
85.4 Assignment of inspectors.
85.5 Uninspected shrimp excluded from inspected establishments.
85.6 General requirements for plant and equipment.
85.7 General operating conditions.
85.8 Code marking.
85.9 Processing.
85.10 Examination after processing.
85.11 Labeling.
85.12 Certificates of inspection; warehousing and export permits.
85.13 Inspection fees.
85.14 Suspension and withdrawal of inspection service.

Subpart B—Inspection of Canned Oysters

85.16 Application for inspection service.
85.17 Granting or refusing inspection service; cancellation of application.

Sec.
85.18 Inspection periods.
85.19 Assignment of inspectors.
85.20 Uninspected oysters excluded from inspected establishments.
85.21 General requirements for plant and equipment.
85.22 General operating conditions.
85.23 Code marking.
85.24 Processing.
85.25 Examination after canning.
85.26 Labeling.
85.27 Certificates of inspection; warehousing and export permits.
85.28 Inspection fees.
85.29 Suspension and withdrawal of inspection service.

AUTHORITY: §§ 85.1 to 85.29 issued under sec. 701, 52 Stat. 1055; 21 U. S. C. 371.

SUBPART A—INSPECTION OF PROCESSED SHRIMP

§ 85.1 *Application for inspection service.* (a) Applications for inspection service on the processing of shrimp under the provisions of section 702a of the Federal Food, Drug, and Cosmetic Act shall be on forms supplied by the Food and Drug Administration, referred to in this subpart as the Administration. The processing of shrimp comprises all the operations, including labeling and storage, necessary to prepare for the market shrimp in any of the following forms: Iced or frozen raw headless, raw peeled or cooked peeled (any of which may be deveined); iced or frozen deveined shrimp, partially or completely peeled (which may be battered and breaded before freezing), and canned shrimp. No application for a regular inspection period filed with the Administration after May 1, preceding such period in any year, shall be considered unless the applicant shows substantial cause for failure to file such application on or before May 1 of such year. A separate application shall be made for each inspection period in each establishment for which the service is applied. Each application for a regular inspection period shall be accompanied by an advance payment of $500.00 as prescribed by § 85.13 (a) (1). Such payment shall be made in the manner prescribed by §85.13 (e).

(b) For the purposes of §§ 85.1 through 85.14, an establishment is defined as a factory where shrimp may be processed and warehouses and cold storage plants under the control and direction of the packer where such shrimp is stored.

§ 85.2 *Granting or refusing inspection service; cancellation of application.* (a) The Secretary of Health, Education, and Welfare may grant the inspection service applied for upon determining that the establishment covered by such application complies with the requirements of § 85.6.

(b) The Secretary may refuse to grant inspection service at any establishment for cause. In case of refusal, the applicant shall be notified of the reason therefor and shall have returned all advance payments and deposits made, less any expenses incurred for preliminary inspection of the establishment or for other purposes incident to such application.

(c) The applicant, by written notice to the Secretary, may withdraw his application for inspection service before July 1 preceding the inspection period covered by the application. In case of such withdrawal, the Secretary shall return to such applicant all advance payments and deposits made, less any salary and other expense incurred incident to such application.

§ 85.3 *Inspection periods.* (a) The regular inspection period in each establishment in which inspection service under §§ 85.1 through 85.14 is granted consists of 9 consecutive months. The date of the beginning of such regular inspection period shall be regarded as the date, on or after July 1 but not later than October 1, specified for the beginning of the service in the application therefor, or such other date as may be specified by amendment to such application and approved; but if the Secretary is not prepared to begin the service on the specified date, then the period shall start on the date on which service is begun.

(b) Extension inspection periods shall begin at the close of the preceding inspection period. Extension inspection periods may be granted for periods of 1 month and/or fractional parts of 1 month, but in no case less than 1 day. Extension inspection periods for 1 month may be granted in such establishment if application therefor, accompanied by a payment of $600.00 as prescribed by § 85.13 (a) (3), is made at least 2 weeks in advance of the close of such preceding inspection period. Applications for extension inspection periods for fractional parts of a month may be accepted when accompanied by the payment prescribed by § 85.13 (a) (3) for such extensions. No regular or extension inspection period shall extend beyond June 30 of any year.

(c) Upon request of the packer, and with the approval of the Administration, such service during any inspection period may be transferred from one establishment to another to be operated by the same packer; but such transfer shall not serve to lengthen any inspection period or to take the place of an extension inspection period. In case of such transfer the packer shall furnish all necessary transportation of inspectors.

(d) The inspection service shall be continuous throughout the inspection period.

§ 85.4 *Assignment of inspectors.* (a) An initial assignment of at least one inspector shall be made to each establishment in which inspection service under §§ 85.1 through 85.14 is granted. Thereafter, the Administration shall adjust the number of inspectors assigned to each establishment and tour of duty of each inspector to the requirements for continuous and efficient inspection.

(b) Any inspector of the Administration shall have free access at all times to all parts of the establishment, to plants supplying materials to the inspected establishment, and to all fishing and freight boats and other conveyances catching shrimp for, or transporting shrimp to, such establishment.

§ 85.5 *Uninspected shrimp excluded from inspected establishments.* (a) No establishment to which inspection service has been granted shall at any time thereafter process shrimp which has not been so inspected or handle or store in such establishment any processed shrimp which has not been so inspected; but this paragraph shall not apply to an establishment after termination of inspection service therein or withdrawal therefrom as authorized by § 85.14.

(b) All shrimp and other ingredients entering into the finished product may be subject to inspection prior to delivery to the establishment or at any time thereafter, and all shrimp processed in such establishment shall be subject to certification under § 85.12.

§ 85.6 *General requirements for plant and equipment.* (a) All exterior openings of the establishment shall be adequately screened, and roofs and exterior walls shall be tight. When necessary, fly traps, fans, blowers, or other approved insect-control devices shall be installed.

(b) Except for raw headless shrimp, which may or may not be deveined, picking and packing rooms shall be separate, provided that this requirement may be waived by the Administration where separation of picking and packing rooms is not necessary for adequate sanitation. Blanching tanks shall not be located in picking room. Fixtures and equipment shall be so constructed and arranged as to permit thorough cleaning. Such rooms shall be adequately lighted and ventilated, and the floors shall be tight and arranged for thorough cleaning and proper drainage. Open drains from picking room shall not enter packing or blanching room. If picking and packing rooms are in separate buildings, such buildings shall be not more than 100 yards apart unless adequate provisions are made to enable efficient inspection.

(c) All surfaces of tanks, belts, tables, flumes, utensils, and other equipment with which either picked or unpicked shrimp come in contact after delivery to the establishment shall be of metal or of other smooth nonporous and easily cleanable materials, provided such materials are not lead or other toxic substances. Metal seams shall be smoothly soldered or smoothly welded.

(d) Adequate supplies of suitable detergents and sanitizing agents approved by the Administration; clean, unpolluted runing water; and, if necessary, steam shall be provided for washing, cleaning, and otherwise maintaining the establishment in a sanitary condition.

(e) Adequate toilet facilities of sanitary type which comply fully with applicable State laws and local ordinances shall be provided.

(f) An adequate number of sanitary washbasins, with liquid or powdered soap, shall be provided in both the picking and packing rooms. Paper towels shall be provided in the packing room. Provision shall be made for sanitizing the hands of employees by the use of suitable sanitizing agents.

(g) Signs requiring employees handling shrimp to wash and sanitize their hands after each absence from post of duty shall be conspicuously posted in the picking and packing rooms and elsewhere about the premises as conditions require.

(h) One or more suitable washing devices and one or more suitable inspection belts shall be installed for the washing and subsequent inspection of the shrimp before processing.

(i) Suitable containers, flumes, chutes, or conveyors shall be provided for removing offal from picking room.

(j) Picking or heading tables shall be equipped with flumes supplied with clean, unpolluted water or with mechanical conveyors for removing the picked or headed shrimp.

(k) Equipment shall be provided for code-marking cans and other immediate containers and master cartons used in packaging other than canned shrimp.

(l) An automatic container-counting device shall be installed in each cannery line.

(m) Each sterilizing retort shall be fitted with at least the following equipment:

(1) An automatic control for regulating temperatures.

(2) An indicating mercury thermometer of a range from 170° F. to 270° F. with scale divisions not greater than 2° F. For steam cook such thermometers shall be installed either within a fitting attached to the shell of the retort or within the door or shell of the retort. For water cook such thermometers shall be installed in the door or shell of the retort below the water level. If the thermometer is installed within a fitting such fitting shall communicate with the chamber of the retort through an opening at least 1 inch in diameter. Such fitting shall be equipped with a bleeder at least ⅛-inch in diameter. If the thermometer is installed within the door or shell of the retort, the bulb shall project at least two-thirds of its length into the principal chamber.

(3) A recording thermometer of a range from 170° F. to 270° F. with scale divisions not greater than 2° F. The bulb of such thermometer shall be installed as prescribed for the indicating mercury thermometer. The case which houses the charts and recording mechanism shall be provided with an approved lock, all keys to which shall be in the sole custody of the inspector.

(4) A pressure gauge of a range from 0 to 30 pounds, with scale divisions not greater than 1 pound and diameter of not less than 5 inches. Such gauge shall be connected to the chamber of the retort by a short gooseneck tube. The gauge shall be not more than 4 inches higher than the gooseneck.

(5) For steam cook, a blow-off vent of at least ¾-inch inside diameter in the top of the retort.

(6) For steam cook, a ⅛-inch bleeder in top of retort.

(n) Each cold storage compartment shall be fitted with at least the following equipment:

(1) An automatic control for regulating temperature.

(2) An indicating thermometer so installed as to indicate accurately the temperature within the storage compartment.

(3) A recording thermometer so installed as to indicate accurately the temperature within the compartment at all times. The case which houses the charts and recording mechanism shall be provided with an approved lock, all keys to which shall be in the sole custody of the inspector.

(o) Provision shall be made for water-glazing where such glazing is necessary to maintain the quality of frozen shrimp. Glazing shall be done with clean, unpolluted water.

(p) Provision shall be made for immediate icing or cold storage of all packaged shrimp which is destined for sale as unfrozen shrimp.

(q) Suitable space and facilities shall be provided for the inspector to prepare records and examine samples, and for the safekeeping of records and equipment.

§ 85.7 *General operating conditions.* (a) Plants supplying raw headless or frozen raw headless shrimp to an inspected establishment, decks and holds of all boats catching shrimp for or transporting shrimp to an inspected establishment, and the bodies of other conveyances so transporting shrimp shall be kept in a sanitary condition.

(b) Inspected establishments, plants supplying inspected establishments, freight boats, and other conveyances serving such establishments shall accept only fresh, clean, sound shrimp. The shrimp shall be iced or refrigerated immediately after they are caught, and shall be kept adequately iced or refrigerated until delivery to the establishment.

(c) After delivery of each load of shrimp to the establishment, decks and holds of each boat and the body of each other conveyance or container making such delivery shall be washed down with clean, unpolluted water, and all debris shall be cleaned therefrom before such boat or other conveyance or container leaves the establishment premises.

(d) Before being headed, picked, or deveined, the shrimp shall be adequately washed with clean, unpolluted water and then passed over the inspection belt and culled to remove all shrimp that are filthy, decomposed, putrid, or otherwise unfit for food, and all extraneous material.

(e) Offal from picking tables shall not be piled on the floor, but shall be placed in suitable containers for frequent removal, or shall be removed by flumes, conveyors, or chutes. Offal, debris, or refuse from any source whatever shall not be allowed to accumulate in or about the establishment.

(f) Shrimp shall be picked into flumes that immediately remove the picked meats from the picking tables; except that shrimp may be picked into seamless containers of not more than 3 pints capacity if the picked meats are not held in such containers for more than 20 minutes before being flumed or conveyed from the picking tables. If shrimp are picked into such containers, the containers shall be cleaned and sanitized as often as may be necessary to maintain them in a sanitiary condition, but in no case less frequently than every 2 hours. Whenever a picker is absent from his or her post of duty, the container used by such picker shall be cleaned and sanitized before picking is resumed. For the purposes of this paragraph, the term "picked" shall include the operation whereby a portion of the shell is removed, leaving the tail in place, and the back of the shrimp is sliced open to remove the alimentary canal or vein.

(g) Picked shrimp being transported from one building to another shall be properly covered and protected against contamination.

(h) From the time of delivery to the establishment up to the time of final processing, shrimp shall be handled expeditiously and under such conditions as to prevent contamination or spoilage. Shrimp other than that to be canned shall be precooled immediately after the final cleaning or blanching operation to a temperature not exceeding 50° F. if it is to be packaged immediately, or to a temperature not exceeding 40° F. if it is not to be packaged immediately. If such shrimp are to be frozen, they shall be placed in the freezing compartment within 1 hour after final preparation.

(i) If batter is employed, it shall be used within 1 hour after it is prepared. The temperature of the batter shall not exceed 50° F.

(j) The packer shall destroy for food purposes under the immediate supervision of the inspector all shrimp in his possession condemned by the inspector as filthy, decomposed, putrid, or otherwise unfit for food. Shrimp condemned on boat or unloading platform shall not be taken into the icebox or picking room.

(k) Raw materials other than shrimp that enter into the finished product shall not be used if condemned by the inspector as unfit for food. Such condemned raw materials shall be segregated from usable materials and be held for disposal as directed by the inspector, or they may be destroyed forthwith by the packer if he so desires.

(l) All portions of the establishment shall be adequately lighted to enable the inspector to perform his duties properly.

(m) All floors and other parts of the establishment, including unloading platforms, and all fixtures, equipment, and utensils shall be cleaned as often as may be necessary to maintain them in a sanitary condition. Containers for mixing or holding batter shall be adequately cleaned and sanitized before they are used for a new batch of batter. Equipment for applying batter shall be adequately cleaned and sanitized at least once each hour while in operation.

(n) The packer shall require all employees handling shrimp to wash and sanitize their hands after each absence from post of duty, and to observe other proper habits of cleanliness.

(o) The packer shall not knowingly employ in or about the establishment any person afflicted with an infectious or contagious disease, or with any open sores on exposed portions of the body.

§ 85.8 *Code marking.* (a) Permanently legible code marks shall be placed on all immediate containers at the time of packaging. Such marks shall show at least:

(1) The date of packing;

(2) The establishment where packed; and

(3) The size of the shrimp when such shrimp are graded for size and are not in containers through which they are clearly visible.

Corresponding code marks shall also be placed on the master cartons containing individual packages of shrimp other than canned.

(b) Keys to all code marks shall be given to the inspector.

(c) Each lot shall be stored separately pending final inspection, with a space of not less than 6 inches between stacks of each lot. For the purposes of the regulations in this part, all cans or other containers bearing the same code marks shall be regarded as comprising a lot.

§ 85.9 *Processing.* (a) The closure of the can or other immediate container and the time and temperature of sterilizing the canned shrimp shall be adequate to prevent bacterial spoilage.

(b) The following times and temperatures shall be the minimums employed for the containers indicated:

DRY PACK

Kind of container and liner	Size	Initial temperature	Time at 240° F.	Time at 250° F.
			Minutes	*Minutes*
Tin:				
1-piece liner	211 x 400 and smaller.	70° F.	80	60
No liner	do	70° F.	70	50
	307 x 208	70° F.	70	50
	307 x 400	70° F.	75	55

WET PACK

Kind of container and size	Initial temperature	Time at 240° F.	Time at 250° F.
		Minutes	*Minutes*
Tin:			
211 x 400 (and smaller)	90° F.	25	13
307 x 208	90° F.	25	13
307 x 400	90° F.	25	13
502 x 510	90° F.	27	16
Glass: 2 to 9 fluid ounces, inclusive		22	14

For wet-pack shrimp in cans 307 x 400 and smaller, a cook of 12 minutes at 250° F., and for wet-pack shrimp in cans 502 x 510, a cook of 15 minutes at 250° F., may be approved if adequate provisions are made to insure an initial temperature of not less than 120° F. in each individual can. For the purposes of this section, initial temperature is defined as the average temperature of the contents of the container at the moment steam is admitted to the sterilizing retort.

(c) For steam cook, blow-off vent shall be open during the coming-up period until the mercury thermometer registers at least 215° F. Bleeders shall emit steam during the entire cooking period.

(d) The method of freezing is not specified by the regulations in this part. Whatever method is used must be such as will produce a hard-frozen product in a sufficiently short time to prevent decomposition. Bulk packages containing 5 pounds or more of shrimp per package shall be hard frozen within 24 hours; smaller packages should be hard frozen within 12 hours. After freezing, the shrimp shall be stored in such a manner that its temperature does not exceed 0° F., and shall be handled in such manner as will maintain the hard-frozen condition.

(e) The storage temperatures for shrimp that are not frozen or canned are as follows:

(1) Cooked and peeled shrimp shall be stored at a room temperature not exceeding 35° F.

(2) Raw headless shrimp shall be stored at a room temperature not exceeding 35° F., except that it may be stored at a higher room temperature if sufficiently iced at all times to prevent spoilage.

(f) The inspector shall identify each record on the thermometer chart with the code mark of the lot to which such record relates and the date of such record. The Administration shall keep such charts for at least 5 years, and upon request shall make them available to the packer.

(g) The packer shall keep for at least 1 year all shipping records covering shipments from each lot, and upon request shall furnish such records to any inspector of the Administration.

§ 85.10 *Examination after processing.* (a) Adequate samples shall be drawn by the inspector from each lot of processed shrimp and shall be examined to determine whether or not such processed shrimp conforms to all requirements of the Federal Food, Drug, and Cosmetic Act, amendments thereto, and regulations thereunder.

(b) The packer shall destroy for food purposes, under the immediate supervision of the inspector, all processed shrimp condemned by the inspector as not complying with § 85.9 (a), or as filthy, decomposed, putrid, or otherwise unfit for food.

§ 85.11 *Labeling.* (a) Labels on shrimp packed and certified under §§ 85.1 through 85.14 may bear a mark attesting to such packing and certification. Depending upon the type of processing, such marks, if used, shall read as follows:

(1) For canned shrimp: "Production supervised by U. S. Food and Drug Administration."

(2) For frozen shrimp: "Packing and freezing supervised by U. S. Food and Drug Administration. Perishable product—Not warranted against mishandling after freezing."

(3) For fresh, iced, or refrigerated shrimp: "Packing supervised by U. S. Food and Drug Administration. Perishable product—Not warranted against mishandling after packing."

Such marks if used shall be plainly and conspicuously displayed in type of uniform size and style on a strongly contrasting uniform background. The marks referred to in subparagraphs (2) and (3) of this paragraph shall not be used on the master carton unless such marks will be defaced by the opening of the cartons.

(b) Labels on inspected processed shrimp, other than canned shrimp, not bearing the marks referred to in paragraph (a) (2) and (3) of this section, and all master cartons for inspected shrimp other than canned shrimp, shall bear the statement "Perishable—Keep frozen" or "Perishable—Keep refrigerated," whichever is applicable to the product.

(c) Two proofs, or one proof and one photostat thereof, or eight specimens of all labeling intended for use on inspected shrimp, or on or within the cases therefor, shall be submitted to the Administration for approval. If proofs or photostat and proof are submitted, eight specimens of the labeling shall be sent to the Administration after printing. The Administration is authorized to approve labeling for use on or with processed shrimp inspected under §§ 85.1 through 85.14; approval shall be subject to the condition that such labeling shall be so used as to comply with the provisions of the Federal Food, Drug, and Cosmetic Act, amendments thereto, and regulations thereunder. The Administration is also authorized to revoke any such approval for cause. The Administration shall not approve labeling for processed shrimp intended for export under the provisions of § 85.12 (e).

(d) No commercial brand or brand name appearing on labeling approved as authorized under paragraph (c) of this section and bearing the marks described in paragraph (a) of this section, and no labeling simulating any such approved labeling, shall be used, after such approval, on processed shrimp other than that which has been handled, prepared, packed, and stored in compliance with all provisions of §§ 85.1 through 85.14; but this section shall not apply to any packer's labeling not bearing such mark after termination of inspection or withdrawal thereof as authorized by § 85.14 or to any distributor's labeling not bearing such mark after written notice by the owner thereof to the Administration that the use of such labeling on inspected processed shrimp has been discontinued and will not be resumed.

(e) Shrimp labeling authorized by paragraph (a) of this section or approved under paragraph (c) of this section shall be used only as authorized by §§ 85.1 through 85.14. Unauthorized use of such labeling renders the user liable to the penalties prescribed by the Federal Food, Drug, and Cosmetic Act, as amended.

§ 85.12 *Certificates of inspection; warehousing and export permits.* (a) After finding that the processed shrimp comprising any parcel has been handled, prepared, and packed in compliance with all provisions of §§ 85.1 through 85.14, bears labeling approved as authorized under § 85.11 (c), and complies with all the provisions of the Federal Food, Drug, and Cosmetic Act, amendments thereto, and regulations thereunder, the inspector shall issue a certificate showing that such processed shrimp so complies. The certificate shall specify the code marks to which it applies, the quantity of the parcel so marked, the place where such parcel is stored, the size of the shrimp, the size and kind of containers, the type of pack, the commercial brand name on the labels, the quality grade of the shrimp if it is fancy, the condition of the shrimp if it is broken or if it is substandard in fill and the destination of the lot if known. Such certificate shall become void if such labeling is removed, altered, obliterated, or replaced, or if mishandling, improper storage, or other circumstances so change the product that it no longer complies with the requirements for the issuance of a certificate; but such processed shrimp may be relabeled under the supervision of an inspector and recertified if the inspector finds that, after being relabeled, it complies with the requirements laid down by this paragraph for the issuance of a certificate.

(b) Unless covered by certificate, processed shrimp shall be moved from an inspected establishment only for storage authorized under paragraph (c) of this section, or for export authorized under paragraph (e) of this section, or for destruction as provided by § 85.10 (b).

(c) Applications to move unlabeled processed shrimp for storage in a warehouse or cold storage plant elsewhere than in the establishment where such shrimp was processed shall be on forms supplied by the Administration. The application shall give the name and location of the warehouse or cold storage plant in which such processed shrimp is to be stored, and shall be accompanied by an agreement signed by the operator of such warehouse or cold storage plant that inspectors shall have free access at all times to all processed shrimp so stored and that conditions which will preserve the identity of each parcel of such processed shrimp shall be continuously maintained pending issuance of a certificate thereon or removal as authorized by paragraph (d) of this section. If such application is approved and it appears to the inspector that the processed shrimp comprising any parcel has been packed in compliance with §§ 85.1 through 85.14 and conforms, except for the absence of labeling, to all requirements of the Federal Food, Drug, and Cosmetic Act, amendments thereto, and regulations thereunder, the inspector shall issue to the applicant, on his request, a warehousing permit covering such processed shrimp. Such permit shall specify the code marks to which it applies, the quantity of the parcel so marked, the places from and to which such parcel is to be moved, the size of the shrimp, the size and kind of containers, the type of pack, whether or not it is fancy grade, the condition of the shrimp if it is broken or if it is substandard in fill, and, if such be the case, that it is intended for export under paragraph (e) of this section. When any provision of the agreement is violated, the Administration may revoke any permit issued pursuant to such agreement, and may also revoke its approval of the application for warehousing or cold storage which accompanied such agreement.

(d) Unless covered by certificate, processed shrimp stored under the authority of paragraph (c) of this section shall be moved from the warehouse or cold storage plant where stored only for re-storage under such authority, or for return upon written permission of the inspector to the establishment where processed, or for export authorized under paragraph (e) of this section, or for destruction as provided by § 85.10 (b).

(e) An application to export processed shrimp under the provisions of section 801 (d) of the act shall be accompanied by the original or a verified copy of the specifications of the foreign purchaser; if required by the Administration, evidence showing that such processed shrimp is not in conflict with the laws of the country to which it is intended for export; and, if shipment of labeled processed shrimp is specified or directed, eight specimens of the labeling therefor. If processed shrimp prepared or packed according to such specifications is not in conflict with the laws of such country, the Administration shall direct the inspector to issue to the applicant an export permit covering such processed shrimp comprising any parcel ordered by such purchaser under such specifications, when the inspector finds that such processed shrimp was packed in compliance with the requirements of §§ 85.1 through 85.14 regarding sanitary conditions and processing; is not filthy, decomposed, putrid, or otherwise unfit for food; accords to such specifications; and is labeled on the outside of the shipping package to show that it is intended for export. Such permit shall specify the code marks to which it applies and the quantity of the parcel so marked, and shall show that such processed shrimp was packed under sanitary conditions, is wholesome, and accords to such specifications. The applicant shall furnish to the inspector documentary evidence showing the exportation of all such processed shrimp.

§ 85.13 *Inspection fees.* (a) (1) Except as otherwise provided by the regulations in this part, an initial payment of $500.00 shall accompany each application; thereafter, eight additional advance payments of $500.00 shall be made on or before the first day of each month beginning July 1 and continuing through February 1 for the regular inspection period; except that the Administration may require the full amount of advance payments prescribed by this paragraph to accompany the application of an applicant who has defaulted in any payment due for any prior packing season.

(2) Whenever it is determined, without hearing, by the Administration that an establishment having the inspection service has been damaged by wind, fire, flood, or other calamity, to such an extent that packing operations cannot be resumed before the end of the fiscal year then current, no advance payments falling due after such calamity shall be required from the packer for that fiscal year; but whenever it is determined, without hearing, by the Administration that an establishment having the inspection service has been so damaged by any such calamity that operations must be suspended temporarily, but can be resumed before the end of the fiscal year then current, advance payments falling due after such calamity and before the month of resumption of operations shall be postponed until operations are resumed, and thereupon shall be paid in equal monthly installments during the period between the time of resumption of operations and June 1 of the fiscal year then current: *Provided,* That in the event of a determination described in this subparagraph the total payments and deposits made by the packer involved shall be charged with the cost of the service made available for the establishment without regard to the method provided hereinafter for computing charges against payments and deposits for shrimp received, and the balance of the total payments and deposits for shrimp received remaining after such charges shall be refunded by the Administration to the packer after the completion of the fiscal year.

(3) Each application for an extension inspection period of 1 month shall be accompanied by a payment of $600.00, and at subsequent monthly intervals thereafter additional payments of $600.00 shall be made; but if the final payment is to cover a period of less than 30 days, then such payment shall be at the rate of $20.00 for each day of such period.

(b) (1) In addition to the payments prescribed in paragraph (a) of this section, advance deposits based upon the quantity of shrimp received by the subscribing establishment shall be made to underwrite adequately the cost of the inspection service. Such deposits shall be paid in advance in amounts of not less than $300.00, unless the Administration on an estimate of receipt of shrimp authorizes other amounts, and shall be computed at the rate of 20 cents per 100 pounds of whole raw shrimp, or 35 cents per 100 pounds of raw headless shrimp, received by the plant. For the purposes of this section, the quantity of shrimp received by an establishment shall be determined by weighing on a suitable scale immediately after such shrimp leaves the initial inspection belt: *Provided, however,* That other arrangements for determining accurately the weight of shrimp received may be employed if approved in advance by the Administration. A record of such weights shall be maintained and made available to the inspector upon his request. Any advance deposits in excess of those required for actual shrimp received for the fiscal year (July 1 through June 30) shall be refunded to the packer by the Administration after the completion of the fiscal year.

(2) Deposits for shrimp received as computed under paragraph (b) (1) of this section, together with production deposits prescribed for oysters canned under § 85.28 (b) (1), shall be charged with the balance of the total cost of the inspection service that has not been provided for by the combined total payments under paragraph (a) of this section and § 85.28 (a), in the case of canned oysters. The balance of the deposits remaining for shrimp received after such charges have been made shall be refunded by the Administration to the packers after the completion of the fiscal year, in the ratio which each packer's deposits for shrimp received and production deposits for oysters canned bears to the combined total of such deposits for shrimp received and oysters canned by all packers for the fiscal year.

(3) When inspection service is withdrawn from an establishment as authorized under § 85.14 (a), the Administration shall not return to the packer any advance payments and/or deposits required to the date of withdrawal of the service. Such payments and/or deposits shall be charged with the cost of the service made available for the establishment, without regard to the method described in this section, and the balance which would have accrued to such packer shall remain to the credit of the Food and Drug Administration in the special account "Salaries and Expenses, Certification and Inspection Services."

(c) A separate fee shall be paid to cover all expenses, incurred in accordance with the regulations of the United States Government, for salary, travel, subsistence, and other purposes incident to inspection described under § 85.4 (b) of suppliers of any materials to establishments under the inspection service or for the purpose of issuing a certificate or warehousing or export permit on processed shrimp stored or held at any place other than an establishment to which a seafood inspector is then assigned.

(d) When the processing plant and the warehouse or cold storage plant of an establishment are located at different points of such distance apart that transportation between them is required for the inspector to perform his duties in the establishment, the packer shall furnish such transportation or shall pay a separate fee to cover all expenses therefor.

(e) All payments required by the regulations in this part shall be by bank draft or certified check, collectible at par, drawn to the order of the Treasurer, United States, and payable at Washington, D. C. All such drafts and checks, except those for the payment required by § 85.1 (a), shall be delivered to the inspector and promptly scheduled to the Food and Drug Administration, Department of Health, Education, and Welfare, Washington, D. C., whereupon after appropriate records thereof have been made, they shall be transmitted to the Chief Disbursing Officer, Division of Disbursement, Treasury Department, for deposit to the special account "Certification and Inspection Services, Food and Drug Administration."

(f) All refunds to the packers shall be by check drawn on the Treasury of the United States pursuant to refund vouchers duly certified and approved by the designated administrative officers.

§ 85.14 *Suspension and withdrawal of inspection service.* (a) The Administration may suspend and the Secretary may withdraw inspection service in any establishment:

(1) Upon failure of the packer to comply with any applicable provision of §§ 85.1 through 85.14; or

(2) Upon the dissemination by the packer or any person in privity with him of any representation that is false or misleading in any particular regarding the application to any seafood of the inspection service provided by the regulations in this part.

(b) When inspection service is suspended in an establishment, as authorized by paragraph (a) of this section, the Administration shall not lengthen the inspection period in such establishment to compensate for any of the time of suspension.

SUBPART B—INSPECTION OF CANNED OYSTERS

§ 85.16 *Application for inspection service.* (a) Applications for inspection service on canned oysters under the provisions of section 702a of the Federal Food, Drug, and Cosmetic Act shall be on forms supplied by the Food and Drug Administration, referred to in this subpart as the administration. No application for a regular inspection period filed with the Administration after September 1 preceding such period in any year shall be considered unless the applicant shows substantial cause for failure to file such application on or before September 1 of such year. The opening date of the canning season in each State shall be the date set by the State agency responsible for controlling the opening date of the canning season in that State. A separate application shall be made for each inspection period in each establishment for which the service is applied. Each application for a regular inspection period shall be accompanied by a payment of $600.00 as prescribed by § 85.28 (a) (1). Such deposit shall be paid in the manner prescribed by § 85.28 (e).

(b) For the purpose of §§ 85.16 through 85.29, an establishment is defined as a factory where oysters may be processed and warehouses under the control and direction of the packer where such canned oysters are stored.

§ 85.17 *Granting or refusing inspection service; cancellation of application.* (a) The Secretary of Health, Education, and Welfare may grant the inspection service applied for upon determining that the establishment covered by such application complies with the requirements of § 85.21.

(b) The Secretary may refuse to grant the inspection service at any establishment for cause. In case of refusal the applicant shall be notified of the reason therefor and shall have returned to him all advance payments and production deposits made, less any expenses incurred for preliminary inspection of the establishment, or for other purposes incident to such application.

(c) The applicant, by written notice to the Secretary, may withdraw his application for inspection service before an inspector is assigned to the establishment. In case of such withdrawal, the Secretary shall return to such applicant all advance payments and production deposits made, less any salary and other expense incurred incident to such application.

§ 85.18 *Inspection periods.* (a) The regular inspection period in each establishment in which inspection service under §§ 85.16 through 85.29 is granted consists of 4 consecutive months. The date of the beginning of such regular inspection period shall be regarded as the date, on or after October 1 but not later than March 1, specified for the beginning of the service in the application therefor, or such other date as may be specified by amendment to such application and approved; but if the Secretary is not prepared to begin the service on the specified date then the period shall start on the date on which service is begun.

(b) Extension inspection periods shall begin at the close of the preceding inspection period. Extension inspection periods may be granted for periods of 1 month and/or fractional parts of 1 month, but in no case less than 1 day. Extension inspection periods for 1 month may be granted in such establishment if application therefor, accompanied by a payment of $600.00, as prescribed by § 85.28 (a) (3), is made at least 2 weeks in advance of the close of such preceding inspection period. Applications for extension inspection periods for fractional parts of a month may be accepted when accompanied by the payment prescribed by § 85.28 (a) (3) for such extensions. No regular or extension inspection period shall extend beyond June 30 of any year.

(c) Upon request of the packer, and with the approval of the Administration, such service during any inspection period may be transferred from one establishment to another to be operated by the same packer; but such transfer shall not serve to lengthen any inspection period or to take the place of an extension inspection period. In case of such transfer the packer shall furnish all necessary transportation of inspectors.

(d) The inspection service shall be continuous throughout the inspection period.

§ 85.19 *Assignment of inspectors.* (a) An initial assignment of at least one inspector shall be made to each establishment in which inspection service under §§ 85.16 through 85.29 is granted. Thereafter, the Administration shall adjust the number of inspectors assigned to each establishment and tour of duty of each inspector to the requirements for continuous and efficient inspection.

(b) Any inspector of the Administration shall have free access at all times to all parts of the establishment and to all fishing and freight boats and other conveyances dredging oysters for or transporting oysters to such establishments.

§ 85.20 *Uninspected oysters excluded from inspected establishments.* (a) No establishment to which inspection service on canned oysters has been granted shall at any time thereafter can oysters that have not been so inspected, or handle or store in such establishment any canned oysters that have not been so inspected; but this paragraph shall not apply to an establishment after termination of inspection service therein, or withdrawal therefrom as authorized by § 85.29.

(b) All oysters delivered to or held in an inspected establishment may be subject to inspection, but certificates of inspection shall be issued under § 85.27 only on canned oysters.

§ 85.21 *General requirements for plant and equipment.* (a) All exterior openings of the cannery, including those of the shucking sheds, shall be adequately screened, and roofs and exterior walls shall be tight. When necessary, fly traps, fans, blowers, or other approved insect-control devices shall be installed.

(b) Shucking sheds and packing rooms shall be separate, and fixtures and equipment shall be so constructed and arranged as to permit thorough cleaning. Such sheds and rooms shall be adequately lighted and ventilated, and the floors shall be tight and arranged for thorough cleaning and proper drainage. Open drains from shucking shed shall not enter packing room. If shucking shed and packing room are in separate buildings, such buildings shall be not more than 100 yards apart, unless adequate provisions are made to enable efficient inspection.

(c) All surfaces of washers, tanks, belts, tables, flumes, utensils, and other equipment with which unshucked or shucked oysters come in contact after delivery to the establishment shall be of metal or of other smooth nonporous and easily cleanable material, provided such materials are not lead or other toxic substances. Metal seams shall be smoothly soldered or smoothly welded. Shucking tables shall be so constructed as to preclude contamination of working surfaces or products thereon from foot traffic or wheelbarrows or other containers used in delivering steamed oysters to such tables.

(d) Adequate supplies of suitable detergents and sanitizing agents approved by the Administration; clean, unpolluted running water; and steam shall be provided for washing, cleaning, and otherwise maintaining the establishment in a sanitary condition.

(e) Adequate toilet facilities of sanitary type which comply fully with applicable State laws and local ordinances shall be provided.

(f) An adequate number of sanitary washbasins, with liquid or powdered soap, shall be provided in both the shucking shed and the packing room. Paper towels shall be provided in the packing room.

(g) Signs requiring employees handling oysters to wash their hands after each absence from post of duty shall be conspicuously posted in the shucking shed and packing room and elsewhere about the premises as conditions require.

(h) One or more suitable washing devices and one or more suitable inspection belts shall be installed for the washing and subsequent inspection of the oysters before delivery for steaming or other means of opening.

(i) If steam boxes are used for opening the oysters, they shall be provided with adequate steam inlets, exhausts, drains, a safety valve, and a pressure gauge.

(j) Suitable means shall be provided for removing shells and debris from shucking shed.

(k) One or more suitable devices shall be provided for removing shell and grit from shucked oysters, for washing such oysters, and for their subsequent drainage.

(l) One or more suitable inspection belts shall be installed for the inspection of shucked oysters.

(m) Equipment shall be provided for code-marking cans.

(n) An automatic container-counting device shall be installed in each cannery line.

(o) Each sterilizing retort shall be fitted with at least the following equipment:

(1) An automatic control for regulating temperatures.

(2) An indicating mercury thermometer of a range from 170° F. to 270° F., with scale divisions not greater than 2° F., installed either within a fitting attached to the shell of the retort or within the door or shell of the retort. If the thermometer is installed within a fitting, such fitting shall communicate with the chamber of the retort through an opening at least 1 inch in diameter. Such fitting shall be equipped with a bleeder at least ⅛-inch in diameter. If the thermometer is installed within the door or shell of the retort, the bulb shall project at least two-thirds of its length into the principal chamber.

(3) A recording thermometer of a range from 170° F. to 270° F., with scale divisions not greater than 2° F. The bulb of such thermometer shall be installed as prescribed for the indicating mercury thermometer. The case which houses the charts and recording mechanism shall be provided with an approved lock, all keys to which shall be in the sole custody of the inspector.

(4) A pressure gauge of a range from 0 to 30 pounds, with scale divisions not greater than 1 pound and diameter of not less than 5 inches. Such gauge shall be connected to the chamber of the retort by a short gooseneck tube. The gauge shall be not more than 4 inches higher than the gooseneck.

(5) A blow-off vent of at least ¾-inch inside diameter in the top of the retort.

(6) A ⅛-inch bleeder in top of the retort.

(p) Suitable space and facilities shall be provided for the inspector to prepare records and examine samples and for the safekeeping of records and equipment.

§ 85.22 *General operating conditions.* (a) The decks and holds of all boats tonging or dredging oysters for or transporting oysters to an inspected establishment, and the bodies of other conveyances so transporting oysters shall be kept in a sanitary condition. Such boats shall be equipped with adequate means for protecting the oysters against contamination with bilge water.

(b) Inspected establishments, freight boats, and other conveyances serving such establishments shall accept only live, clean, sound oysters taken from unpolluted areas. When necessary, ice or other suitable refrigeration shall be provided to prevent spoilage.

(c) After delivery of each load of oysters to the establishment, decks and holds of each boat and the body of each other conveyance or container making such delivery shall be washed down with clean, unpolluted water, and all debris shall be cleaned therefrom before such boat or other conveyance or container leaves the establishment premises.

(d) Before being steamed or opened by other means, the oysters shall be washed with clean, unpolluted water and then passed over the inspection belt and culled to remove dirty, muddy, dead, or decomposed oysters and extraneous material. Muddy oysters may be returned to the washer for rewashing.

(e) As often as is necessary to maintain sanitary conditions, unloading platforms and equipment shall be washed with clean, unpolluted water, and all debris shall be cleaned therefrom.

(f) Shells shall be removed from the shucking shed continuously.

(g) Offal, debris, or refuse from any source whatever shall not be allowed to accumulate in the cannery or, except for shells, about the premises. Shells shall not be allowed to accumulate about the premises in such a manner as to create a nuisance.

(h) The delivery of steamed oysters to shuckers by means of manually rolling, trundling, or wheelbarrowing such oysters on or above shucking tables will not be permitted.

(i) Shucking knives and shucking cups shall be thoroughly washed with soap and water and chlorinated before use each day. Chlorine solution shall be maintained at a strength of 200 parts per million.

(j) No shucked oysters shall be returned to shucker after delivery to the weigher. Shucking cups shall be cleaned and sanitized after each delivery to the weigher.

(k) Shucked oysters being transported from one building to another shall be properly covered and protected against contamination.

(l) The shucked oysters shall be washed, separated from the shell and grit by suitable devices, and then immediately drained. The time of washing shall not exceed the minimum time necessary for cleansing.

(m) From the time of delivery to the cannery up to the time of final processing, oysters shall be handled expeditiously and under such conditions as to prevent contamination or spoilage.

(n) The packer shall destroy for food purposes under the immediate supervision of the inspector all oysters in his possession condemned by the inspector as filthy, decomposed, putrid, or unfit for food. Oysters condemned on the boat or on the unloading platform shall not be taken into the cannery, but shall be either destroyed or returned to a bedding ground.

(o) All portions of the establishment shall be adequately lighted to enable the inspector to perform his duties properly.

(p) All floors and other parts of the establishment including unloading platforms, and all fixtures, equipment, and utensils shall be cleaned as often as may be necessary to maintain them in a sanitary condition.

(q) The packer shall require all employees handling oysters to wash their hands after each absence from post of duty and to observe other proper habits of cleanliness.

(r) The packer shall not knowingly employ in or about the establishment any person afflicted with an infectious or contagious disease or with any open sores on exposed portions of the body.

§ 85.23 *Code marking.* (a) Code marks shall be affixed to all cans and other immediate containers before they are placed in the processing retorts. Such marks shall show at least:

(1) The date of packing;

(2) The establishment where packed;

(3) The conveyance; and

(4) The size of the oysters when such oysters are graded for size.

(b) Keys to all code marks shall be given to the inspector.

(c) Each lot shall be stored separately pending final inspection, with a space of not less than 6 inches between stacks of each lot. For the purposes of the regulations in this part all cans or other containers bearing the same code marks shall be regarded as comprising a lot.

§ 85.24 *Processing.* (a) The closure of the can or other immediate container and the time and temperature of sterilizing the canned oysters shall be adequate to prevent bacterial spoilage.

(b) The following times and temperatures shall be the minimum employed for the containers indicated:

CANNED OYSTERS

Size	Initial temperature (°F.)	Time at 240° F.	Time at 250° F.
		Minutes	*Minutes*
211 x 212 211 x 300 211 x 306 211 x 400	70 130	24 23	14 13
307 x 400	70	28	14
307 x 409	130	27	13

For the purposes of this section, initial temperature is defined as the average temperature of the contents of the container at the moment steam is admitted to the sterilizing retort.

(c) The blow-off vent shall be open during the coming-up period until the mercury thermometer registers at least 215° F. Bleeders shall emit steam during the entire cooking period.

(d) The inspector shall identify each record on the thermometer chart with the code mark of the lot to which such record relates and the date of such record. The Administration shall keep such charts for at least 5 years, and upon request shall make them available to the packer.

(e) The packer shall keep for at least 1 year all shipping records covering shipments from each lot, and upon request shall furnish such records to any inspector of the Administration.

§ 85.25 *Examination after canning.* (a) Adequate samples shall be drawn by the inspector from each lot of canned oysters and shall be examined to determine whether or not such canned oysters conform to all requirements of the Federal Food, Drug, and Cosmetic Act, amendments thereto, and regulations thereunder.

(b) The packer shall destroy for food purposes, under the immediate supervision of the inspector, all canned oysters condemmed by the inspector as not complying with § 85.24, or as filthy, decomposed, putrid, or otherwise unfit for food.

§ 85.26 *Labeling.* (a) Labels on canned oysters packed and certified under §§ 85.16 through 85.29 may bear the mark "Production Supervised by the U. S. Food and Drug Administration." Such mark, if used, shall be plainly and conspicuously displayed, in type of uniform size and style, on a strongly contrasting, uniform background.

(b) Two proofs, or one proof and one photostat thereof, or eight specimens of all labeling intended for use on inspected canned oysters or on or within the cases therefor shall be submitted to the Administration for approval. If proofs or photostat and proof are submitted, eight specimens of the labeling shall be sent to the Administration after printing. The Administration is hereby authorized to approve labeling for use on canned oysters inspected under §§ 85.16 through 85.29. Approval shall be subject to the condition that such labeling shall be so used as to comply with the provisions of the Federal Food, Drug and Cosmetic Act, amendments thereto, and regulations thereunder. The Administration is also authorized to revoke any such approval for cause. The Administration shall not approve labeling for canned oysters intended for export under the provisions of § 85.27 (e).

(c) No commercial brand or brand name appearing on labeling approved as authorized under paragraph (b) of this section and bearing the mark described in paragraph (a) of this section, and no labeling simulating any such approved labeling, shall be used after such approval on canned oysters other than those that have been handled, prepared, and packed in compliance with all provisions of §§ 85.16 through 85.29; but this section shall not apply to any packer's labeling not bearing such mark after termination of inspection or withdrawal thereof as authorized by § 85.29 or to any distributor's labeling not bearing such mark after written notice by the owner thereof to the Administration that the use of such labeling on inspected canned oysters has been discontinued and will not be resumed.

(d) Canned-oyster labeling authorized by paragraph (a) of this section or approved under paragraph (b) of this section shall be used only as authorized by §§ 85.16 through 85.29. Unauthorized use of such labeling renders the user liable to the penalties prescribed by the Food, Drug, and Cosmetic Act, as amended.

§ 85.27 *Certificates of inspection; warehousing and export permits.* (a) After finding that the canned oysters comprising any parcel have been handled, prepared, and packed in compliance with all provisions of §§ 85.16 through 85.29; bear labeling approved as authorized under § 85.26 (b); and comply with all the provisions of the Federal Food, Drug, and Cosmetic Act, amendments thereto, and regulations thereunder, the inspector shall issue a certificate showing that such canned oysters so comply. The certificate shall specify the code marks to which it applies, the quantity of the parcel so marked, the place where such parcel is stored, the size and kind of containers, the commercial brand name on the labels, the condition of the oysters if they are broken or if they are substandard in fill, and the destination of the lot, if known. Such certificate shall become void if such labeling is removed, altered, obliterated, or replaced; but such canned oysters may be relabeled under supervision of an inspector and recertified if the inspector finds that, after being relabeled, they comply with the requirements laid down by this paragraph for the issuance of a certificate.

(b) Unless covered by certificate, canned oysters shall be moved from an inspected establishment only for storage authorized under paragraph (c) of this section, or for export authorized under paragraph (e) of this section, or for destruction as provided by § 85.25 (b).

(c) Applications to move unlabeled canned oysters for storage in a warehouse elsewhere than in the establishment where such oysters were packed shall be on forms supplied by the Administration. The application shall give the name and location of the warehouse in which such canned oysters are to be stored, and shall be accompanied by an agreement signed by the operator of such warehouse that inspectors shall have free access at all times to all canned oysters so stored, and that conditions which will preserve the identity of each parcel of such canned oysters shall be continuously maintained pending issuance of a certificate thereon or removal as authorized by paragraph (d) of this section. If such application is approved and it appears to the inspector that the canned oysters comprising any parcel have been packed in compliance with §§ 85.16 through 85.29 and conform, except for the absence of labeling, to all requirements of the Federal Food, Drug, and Cosmetic Act, amendments thereto, and regulations thereunder, the inspector shall issue to the applicant, on his request, a warehousing permit covering such canned oysters. Such permit shall specify the code marks to which it applies, the quantity of the parcel so marked, the place from and to which such parcel is to be moved, the size of the oysters, the size and kind of containers, and the condition of the oysters if they are broken or if they are substandard in fill and, if such be the case, that they are intended for export under paragraph (e) of this section. When any provision of the agreement is violated, the Administration may revoke any permit issued pursuant to such agreement, and may also revoke its approval of the application for warehousing which accompanied such agreement.

(d) Unless covered by certificate, canned oysters stored under the authority of paragraph (c) of this section shall be moved from the warehouse where stored only for re-storage under such authority, or for return upon written permission of the inspector to the establishment where packed, or for export authorized under paragraph (e) of this section, or for destruction as provided by § 85.25 (b).

(e) An application to export canned oysters under the provisions of section 801 (d) of the act shall be accompanied by the original or a verified copy of the specifications of the foreign purchaser; if required by the Administration, evidence showing that such canned oysters are not in conflict with the laws of the country to which they are intended for export; and, if shipment of labeled canned oysters is specified or directed, eight specimens of the labeling therefor. If canned oysters prepared or packed according to such specifications are not in conflict with the laws of such country, the Administration shall direct the inspector to issue to the applicant an export permit covering such canned oysters comprising any parcel ordered by such purchaser under such specifications, when the inspector finds that such canned oysters were packed in compliance with the requirements of §§ 85.16 through 85.29 regarding sanitary conditions and processing; are not filthy, decomposed, putrid, or otherwise unfit for food; accord to such specifications, and are labeled on the outside of the shipping package to show that they are intended for export. Such permit shall specify the code marks to which it applies and the quantity of the parcel so marked, and shall show that such canned oysters were packed under sanitary conditions, are wholesome, and accord to such specifications. The applicant shall furnish to the inspector documentary evidence showing the exportation of all such canned oysters.

§ 85.28 *Inspection fees.* (a) (1) Except as otherwise provided by the regulations in this part, an initial payment of $600.00 shall accompany each application; thereafter, three additional advance payments of $600.00 each shall be made, as follows: One payment on or before the date of the beginning of the regular inspection period specified in the application for inspection; the remaining two payments on or before the first day of each succeeding month, except that the Administration may require the full amount of all advance payments prescribed by this paragraph to accompany the application of an applicant who has defaulted in any payment due for any prior packing season: *Provided*, That a packer who is concurrently receiving inspection service and making payments under the regulations for the inspection of processed shrimp shall not make any additional payments under this subparagraph.

(2) Whenever it is determined, without hearing, by the Administration that an establishment having the inspection service has been damaged by wind, fire, flood, or other calamity to such an extent that packing operations cannot be resumed before the end of the fiscal year then current, no advance payments falling due after such calamity shall be required from the packer for that fiscal year; but whenever it is determined, without hearing, by the Administration that an establishment having the inspection service has been so damaged by any such calamity that operations must be suspended temporarily, but can be resumed before the end of the fiscal year then current, advance payments falling due after such calamity and before the month of resumption of operations shall be postponed until operations are resumed, and thereupon shall be paid in equal monthly installments during the period between the time of resumption of operations and June 1 of the fiscal year then current: *Provided*, That in the event of a determination described in this subparagraph the total payments and production deposits made by the packer involved shall be charged with the cost of the service made available for the establishment, without regard to the method provided hereinafter for computing charges against payments and production deposits, and the balance of the total payments and deposits remaining after such charges shall be refunded by the Administration to the packer after the completion of the fiscal year.

(3) Each application for an extension inspection period of 1 month shall be accompanied by a payment of $600.00, and at subsequent monthly intervals thereafter additional payments of $600.00 shall be made; but if the final payment is to cover a period of less than 30 days, then such payment shall be at the rate of $20.00 for each day of such period.

(b) (1) In addition to the payments prescribed in paragraph (a) of this section, advance deposits based upon the quantity of oysters canned by the subscribing establishment shall be made to underwrite adequately the cost of the inspection service. Such deposits shall be paid in advance in amounts of not less than $300.00, unless the Administration on an estimate of production authorizes other amounts, and shall be computed at the rate of 15 cents for each case of 48 cans, size 211 x 300. Any advance production deposits in excess of those required for actual oysters canned for the fiscal year (July 1 through June 30) shall be refunded to the packers by the Administration after the completion of the fiscal year.

(2) Production deposits as computed under subparagraph (1) of this paragraph, together with deposits for shrimp received as prescribed under § 85.13 (b) (1), in the case of processed shrimp, shall be charged with the balance of the total cost of the inspection service which has not been provided for by the combined total payments under paragraph (a) of this section and paragraph (a) of § 85.13, in the case of processed shrimp. The balance of the production deposits remaining after such charges have been made shall be refunded by the Administration to the packers after the completion of the fiscal year in the ratio which each packer's production deposits for oysters canned and deposits for shrimp received bears to the combined total of such deposits for oysters canned and shrimp received by all packers for the fiscal year.

(3) When inspection service is withdrawn from an establishment as authorized under § 85.29 (a), the Administration shall not return to the packer any advance payments and/or deposits required to the date of withdrawal of the service. Such payments and/or deposits shall be charged with the cost of the service made available for the establishment, without regard to the method described in this section, and the balance that would have accrued to such packer shall remain to the credit of the Food and Drug Administration in the special account "Salaries and Expenses, Certification and Inspection Services."

(c) A separate fee shall be paid to cover all expenses incurred in accordance with the regulations of the United States Government, for salary, travel, subsistence, and for other purposes incident to inspection for the purpose of issuing a certificate or warehousing or export permit on canned oysters stored or held at any place other than an establishment to which a seafood inspector is then assigned.

(d) When the cannery and the cannery warehouse of an establishment are located at different points of such distance apart that transportation between them is required for the inspector to perform his duties in the establishment, the packer shall furnish such transportation or shall pay a separate fee to cover all expenses therefor.

(e) All payments required by the regulations in this part shall be by bank draft or certified check, collectible at par, drawn to the order of the Treasurer, United States, and payable at Washington, D. C. All such drafts and checks, except those for the payment required by § 85.16 (a), shall be delivered to the inspector and promptly scheduled to the Food and Drug Administration, Department of Health, Education, and Welfare, Washington, D. C., whereupon after appropriate records thereof have been made they shall be transmitted to the Chief Disbursing Officer, Division of Disbursement, Treasury Department, for deposit to the special account "Certification and Inspection Services, Food and Drug Administration."

(f) All refunds to packers shall be by check drawn on the Treasury of the United States pursuant to refund vouchers duly certified and approved by the designated administrative officers.

§ 85.29 *Suspension and withdrawal of inspection service.* (a) The Administration may suspend and the Secretary may withdraw inspection service in any establishment upon failure of the packer to comply with any applicable provision of §§ 85.16 through 85.29 or upon the dissemination by the packer or any person in privity with him of any representation that is false or misleading in any particular regarding the application to any seafood of the inspection service provided by the regulations in this part.

(b) When inspection service is suspended in an establishment, as authorized by paragraph (a) of this section, the Administration shall not lengthen the inspection period in such establishment to compensate for any of the time of suspension.

PART 120—TOLERANCES AND EXEMPTIONS FROM TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

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AUTHORITY: §§ 120.1 to 120.119 issued under sec. 701, 52 Stat. 1055; 21 U. S. C. 371. Interpret or apply sec. 408, 68 Stat. 511; 21 U. S. C. 346a.

DEFINITIONS, INTERPRETATIONS, AND EXEMPTIONS

§ 120.1 *Definitions and interpretations.* (a) Secretary, without qualification, means the Secretary of Health, Education, and Welfare.

(b) Department, without qualification, means the Department of Health, Education, and Welfare.

(c) Commissioner means the Commissioner of Food and Drugs.

(d) Pesticide Branch means the unit established within the Food and Drug Administration charged with administration of the Pesticide Residue amendment to the Federal Food, Drug, and Cosmetic Act (section 408).

(e) Raw agricultural commodities include, among other things, fresh fruits, whether or not they have been washed and colored or otherwise treated in their unpeeled natural form; vegetables in their raw or natural state, whether or not they have been stripped of their outer leaves, waxed, prepared into fresh green salads, etc.; grains, nuts, eggs, raw milk, meats, and similar agricultural produce. It does not include foods that have been processed, fabricated, or manufactured by cooking, freezing, dehydrating, or milling.

(f) Where raw agricultural commodities bearing residues that have been exempted from the requirement of a tolerance, or which are within a tolerance permitted under section 408 are used, the processed foods will not be considered unsafe within the meaning of section 406 if:

(1) The poisonous or deleterious pesticide residues have been removed to the extent possible in good manufacturing practice; and

(2) The concentration of the pesticide in the preserved or processed food when ready to eat is not greater than the tolerance permitted on the raw agricultural commodity.

§ 120.2 *Pesticide chemicals considered unsafe.* (a) In general, pesticide chemicals are not generally recognized as safe for use, for the purpose of section 408 (a), except sulfur, lime, and lime-sulfur.

(b) Upon written request, the Pesticide Branch will advise interested persons whether a pesticide chemical should be considered as poisonous or deleterious, or one not generally recognized by qualified experts as safe.

(c) The training and experience necessary to qualify experts to evaluate the safety of pesticide chemicals for the purposes of section 408 (a) are essentially the same as training and experience necessary to qualify experts to serve on advisory committees prescribed by section 408 (g). (See § 120.11.)

§ 120.3 *Tolerances for related pesticide chemicals.* (a) Pesticide chemicals that cause related pharmacological effects will be regarded, in the absence of evidence to the contrary, as having an additive deleterious action. (For example, pesticide chemicals within each of the following groups have related pharmacological effects: Many chlorinated hydrocarbons, arsenic-containing chemicals, metallic dithiocarbamates, many organic phosphates.)

(b) Tolerances established for such related pesticide chemicals may limit the amount of a common component (such as As_2O_3) that may be present, or may limit the amount of biological activity (such as cholinesterase inhibition) that may be present, or may limit the total amount of related pesticide chemicals (such as chlorinated hydrocarbons) that may be present.

§ 120.4 *Certification of usefulness and residue estimate.* The time period for the Department's consideration of a petition will not begin to run until the Secretary of Agriculture certifies that the pesticide chemical involved is useful and gives an opinion whether the tolerance proposed by the petitioner reasonably reflects the amount of residue likely to result when the pesticide chemical is used in the manner proposed. The tolerance thereafter established ordinarily will not exceed that figure which the Secretary of Agriculture states, in his opinion, reasonably reflects the amounts of residue likely to result.

§ 120.5 *Zero tolerances.* A zero tolerance means that no amount of the pesticide chemical may remain on the raw agricultural commodity when it is offered for shipment. A zero tolerance for a pesticide chemical in or on a raw agricultural commodity may be established because, among other reasons:

(a) A safe level of the pesticide chemical in the diet of two different species of warm-blooded animals has not been reliably determined.

(b) The chemical is carcinogenic to or has other alarming physiological effects upon one or more of the species of the test animals used, when fed in the diet of such animals.

(c) The pesticide chemical is toxic, but is normally used at times when, or in such manner that, fruit, vegetables, or other raw agricultural commodities will not bear or contain it.

(d) All residue of the pesticide chemical is normally removed through good agricultural practice such as washing or brushing or through weathering or other changes in the chemical itself, prior to introduction of the raw agricultural commodity into interstate commerce.

§ 120.6 *Exemptions from the requirement of a tolerance.* (a) An exemption from a tolerance shall be granted when it appears that the total quantity of the pesticide chemical in or on all raw agricultural commodities for which it is useful under conditions of use currently prevailing or proposed will involve no hazard to the public health.

(b) When applied to growing crops, in accordance with good agricultural practice, the following pesticide chemicals are exempt from the requirement of a tolerance:

(1) The following copper compounds: Bordeaux mixture, copper acetate, basic copper carbonate (malachite), copper-lime mixtures, copper oxychloride, copper silicate, copper sulfate basic, copper-zinc chromate, cuprous oxide.

(2) *N*-Octylbicyclo-(2,2,1)-5-heptene-2,3-dicarboximide).

(3) Petroleum oils.

(4) Piperonyl butoxide.

(5) Piperonyl cyclonene.

(6) *N*-Propyl isome.

(7) Pyrethrum and pyrethrins.

(8) Rotenone or derris or cube roots.

(9) Ryania.

(10) Sabadilla.

These pesticides are not exempted from the requirement of a tolerance when applied to a crop at the time of or after harvest.

PROCEDURE FOR FILING PETITIONS

§ 120.7 *Petitions proposing tolerances or exemptions for pesticide residues in or on raw agricultural commodities.* (a) Petitions to be filed with the Department under the provisions of section 408 (d) shall be submitted in duplicate to the Pesticide Branch. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petition shall be accompanied by an advance deposit for fees described in § 120.33. The petition shall state petitioner's mail address to which notice of objection under section 408 (d) (5) may be sent.

(b) Petitions shall include the following data and be submitted in the following form:

------------------------ (Date)

Pesticide Branch,
Food and Drug Administration,
Department of Health, Education, and Welfare,
Washington 25, D. C.

Dear Sirs:

The undersigned, ----------------, submits this petition pursuant to section 408 (d) (1) of the Federal Food, Drug, and Cosmetic Act with respect to the pesticide chemical -----------.

Attached hereto, in duplicate and constituting a part of this petition, are the following:

A. The name, chemical identity, and composition of the pesticide chemical. (If the pesticide chemical is an ingredient of an economic poison, the complete quantitative formula of the resulting economic poison should be submitted. The submission of this information does not restrict the application of any tolerance or exemption granted to the specific formula(s) submitted.)

B. The amount, frequency, and time of application of the pesticide chemical.

C. Full reports of investigations made with respect to the safety of the pesticide chemical. (These reports should include, where necessary, detailed data derived from appropriate animal or other biological experiments in which the methods used and the results obtained are clearly set forth.)

D. The results of tests on the amount of residue remaining, including a description of the analytical method used. (Sufficient information should be submitted about the analytical method to permit competent investigators to apply it successfully.)

E. Practicable methods for removing residue that exceeds any proposed tolerance.

F. Proposed tolerances for the pesticide chemical if tolerances are proposed.

G. Reasonable grounds in support of the petition.

Enclosed is (money order, bank draft, or certified check) for $------, payable to the Food and Drug Administration to cover clerical operations, initial administrative review, and the cost incurred in considering the petition after it has been filed.

Very truly yours,

------------------------ (Petitioner)
Per ------------------------
------------------------ (Indicate authority)
Mail address ------------------------

This petition must be signed by the petitioner or by his attorney or agent, or (if a corporation) by an authorized official.

The data specified under the several lettered headings should be on separate sheets or sets of sheets, suitably identified. If such data have already been submitted with an earlier application, the present petition may incorporate it by reference to the earlier one.

The petitioner will be notified of the date on which his petition is filed.

ALL PETITIONS SHOULD BE SUBMITTED IN DUPLICATE. A SINGLE COPY WILL NOT BE ACCEPTED FOR FILING

(c) Except as noted in paragraph (d) of this section, a petition shall not be accepted for filing if any of the data prescribed by section 408 (d) are lacking or are not set forth so as to be readily understood. Data in a petition entitled to protection as a trade secret will be held confidential and not revealed unless it is necessary to do so in administrative or judicial proceedings under section 408.

(d) The Pesticide Branch shall notify the petitioner within 15 days after its receipt of acceptance or nonacceptance of a petition, and if not accepted the reasons therefor. Copy of the notice shall be sent to the Plant Pest Control Branch, Agricultural Research Service, Department of Agriculture. If accepted, the date of notification becomes the date of filing for the purposes of section 408 (d) (1). If petitioner desires, he may supplement a deficient petition after notification as to deficiencies. Each supplement shall be accompanied by a deposit of fees as specified in § 120.33 (e). If the supplementary material or explanation of petition is deemed acceptable, petitioner shall be notified, and date of such notification becomes the date of filing. If the petitioner does not wish to supplement or explain the petition and requests in writing that it be filed as submitted, the petition shall be filed and the petitioner so notified. The date of such notification becomes the date of filing. The Commissioner shall publish in the FEDERAL REGISTER within 30 days a notice of filing, name of petitioner, and a brief outline of the petition, including description of analytical method or reference to a publication in which it appears, if such publication is generally available.

(e) The Pesticide Branch may request a sample of the pesticide chemical at any time while a petition is under consideration. The Pesticide Branch shall specify in its request for a sample of the pesticide chemical, a quantity which it deems adequate to permit tests of analytical methods used to determine residues of the pesticide chemical and of methods proposed by the petitioner for removing any residues of the chemical that exceed the tolerance proposed. The date used for computing the 90-day limit for the purposes of section 408 (d) (2) shall be moved forward 1 day for each day in excess of 15 from the mailing date of the request taken by the petitioner to submit the sample. If the sample is not submitted within 180 days after mailing date of the request, the petition will be considered withdrawn without prejudice.

(f) The date of receipt from the Secretary of Agriculture of certification as to usefulness shall be the date used for computing the 90-day limit for the purposes of section 408 (d) (2).

(g) Unless the petition is referred to an advisory committee, the Commissioner shall publish in the FEDERAL REGISTER within 90 days after receipt of the certification of usefulness, a regulation establishing a tolerance for residues of of the pesticide chemical or exempting such residues from the necessity of a tolerance, as provided in section 408 (d) (2) of the act.

§ 120.8 *Withdrawal of petitions without prejudice.* In some cases the Pesticide Branch or an advisory committee to which the petition has been referred will notify the petitioner that the petition, while technically complete, is inadequate to justify the establishment of a tolerance or the tolerance requested by petitioner. This may be due to the fact that the data are not sufficiently clear or complete. In such cases, the petitioner may withdraw the petition pending its clarification or the obtaining of additional data. This withdrawal may be without prejudice to a future filing. Upon refiling, the time limitation will begin to run anew from the date of refiling or the date of receipt of certification from the Secretary of Agriculture, whichever is later. A deposit for fees as specified in § 120.33 (f) shall accompany the resubmission of the petition.

§ 120.9 *Substantive amendments to petitions.* After a petition has been filed or referred to an advisory committee, the petitioner may submit additional information or data in support thereof, but in such cases the petition will be given a new filing date or a new initial date of consideration by the advisory committee, and the time limitation will begin to run anew. The additional data shall be accompanied by a deposit of fees as specified in § 120.33 (g).

ADVISORY COMMITTEES

§ 120.10 *Referral of petition to advisory committee.* (a) If within the prescribed period a person filing a petition requests that the petition be referred to an advisory committee, he shall make such request in writing to the Commissioner and forward with such request an advance deposit for fees prescribed by § 120.33 (i) (3).

(b) If further advance deposits are not made upon request of the Commissioner, as provided for in § 120.33 (i) (3), the request for referral of the petition to an advisory committee shall be considered withdrawn, and a tolerance shall be established within 90 days of the date on which the Commissioner requested the further advance deposit.

(c) In case the Commissioner on his own initiative deems it necessary to refer a petition to an advisory committee, he shall, in writing, so inform the person filing the petition.

§ 120.11 *Appointment of advisory committee.* (a) Whenever the referral of a petition or proposal to an advisory committee is requested or the Commissioner otherwise deems such referral necessary, the Commissioner will request the National Academy of Sciences to select qualified experts, including at least one representative from land-grant colleges, willing to serve on the advisory committee. All such experts shall have had sufficient training and experience in biology, medicine, physiology, toxicology, pharmacology, veterinary medicine, or other appropriate science to evaluate the safety of pesticide chemicals. The Commissioner will request the National Academy of Sciences, when it furnishes the names of such experts, to supply a biographical sketch showing the background of their experience and their connection, if any, with academic and commercial institutions.

(b) Each advisory committee shall consist of not less than three experts, at least one of whom is a representative from a land-grant college. The Commissioner may specify a larger number to serve. He shall appoint one member of the committee as chairman, and the chairman shall be the spokesman of the committee for receiving and forwarding reports, and other functions of the committee.

(c) The Commissioner shall appoint the experts so selected and fix their compensation at not to exceed $50.00 per day for each day or part thereof spent in committee meetings and in traveling to and from committee meetings held outside the city of their residence, plus necessary traveling and subsistence expenses while the experts are serving away from their places of residence. Subsistence expenses shall not exceed $25.00 per day.

§ 120.12 *Procedure for advisory committee.* (a) The Commissioner shall submit to the chairman of the committee the petition for tolerances, together with certification by the Secretary of Agriculture and such other relevant, reliable information as may be available. When the Commissioner submits a proposal to an advisory committee, he shall inform the petitioner and furnish him with copies of material other than the petition and certification that is furnished the committee. The chairman of the committee shall acknowledge receipt of the information and readiness of the committee to act. The date of receipt of such information shall be considered the beginning of the period allowed for consideration by the committee. Copy of this acknowledgment shall be forwarded to the petitioner by the chairman of the committee.

(b) A secretariat to advisory committees will be established by the Commissioner. The secretariat shall furnish members of the committee with copies of the proposal or petition, certification from the Secretary of Agriculture, and any data received by the chairman. If the chairman of the committee believes that a meeting of the committee is necessary before making a recommendation, he shall so advise the Commissioner. Such meetings shall be held in Washington, D. C., or such other place as the Commissioner may designate. The Commissioner shall furnish a suitable meeting place for the committee. If a meeting is held, the secretariat shall keep the minutes and provide clerical assistance.

(c) As soon as practicable, but not later than 60 days after receipt of proposal or petition (unless the time has been extended as provided in paragraph (d) of this section), the chairman shall certify to the Commissioner the report of the committee, including any minority report, and shall return the petition for tolerances and the certification by the Secretary of Agriculture. The report will include copies of all relevant material considered by the committee, except that in the case of scientific literature readily available in scientific libraries proper reference may be made to it instead of furnishing actual copies. The report of the advisory committee shall be available for inspection by any interested person after a tolerance or exemption resulting from the petition is published.

(d) If at any time within 60 days, the chairman believes that the advisory committee needs more time, he shall so inform the Commissioner in writing, in which case he shall make the certification contemplated by section 408 (d) (3) of the act within the additional 30 days.

(e) The date of receipt of the committee report will be the date for computing time for the Commissioner to act for the purposes of both sections 408 (d) (3) and (e).

(f) The chairman of the committee, after consultation with the committee members, will inform the National Academy of Sciences of the committee's opinion as to the member who may best represent the committee at a hearing, if one occurs.

(g) More than one petition or proposal may be handled by a committee concurrently.

(h) Persons authorized under section 408 (h) to discuss proposals or petitions with the committee shall notify the chairman and if practicable make appointments through him. The report of the committee shall show the names of persons other than committee members discussing proposals or petitions with the committee. Except for discussions with authorized persons the committee shall not disclose data originating with a petitioner prior to publication of a regulation.

PROCEDURE FOR FILING OBJECTIONS AND HOLDING A PUBLIC HEARING

§ 120.13 *Objections to regulations and requests for hearings.* (a) Objections under section 408 (d) (5) shall be submitted in quintuplicate to the hearing clerk of the Department and shall be accompanied by a filing fee as specified in § 120.33 (h). Each objection to a provision of the regulation shall be separately numbered.

(b) A statement of objections shall not be accepted for filing if:

(1) It fails to establish that the objector is adversely affected by the regulation; or

(2) It does not specify with particularity the provisions of the regulation to which objection is taken; or

(3) It does not state reasonable grounds for each objection raised. Grounds which it is reasonable to conclude are capable of being established by reliable evidence at the hearing and which if proved would call for changing the provisions specified in the objections will be deemed reasonable grounds.

(c) If the statement of objections may not be filed, the Commissioner shall inform the objector of the reasons.

(d) If objections to a regulation issued pursuant to a petition are filed by a person other than the petitioner, the Food and Drug Administration shall send a copy of the objections by registered mail, return receipt requested, to the petitioner at the address given in the petition. Petitioner shall have 2 weeks from the date of receipt of the objections to make written reply.

§ 120.14 *Public hearing; notice.* If the objections and statements filed by any person, when they are considered with the record in the proceeding (including any reply to the objections that the petitioner may have filed) show that the person filing the objections is adversely affected and that the grounds stated in support of the objections are reasonable, the Commissioner shall cause to be published in the FEDERAL REGISTER a notice reciting the objections and announcing a public hearing to receive evidence on them. The notice shall designate the place where the hearing will be held, specify the time within which appearances must be filed, and specify the time (not earlier than 30 days after the date of the notice) when the hearing will start. The hearing shall convene at the place and time announced in the notice but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without other notice than announcement thereof by the presiding officer at the hearing.

§ 120.15 *Presiding officer.* The hearing shall be conducted by a presiding officer, who shall be a hearing examiner appointed as provided in the Administrative Procedure Act and designated by the Commissioner for conducting the hearing. Any such designation may be made or revoked by the Commissioner at any time. Hearings shall be conducted in an informal but orderly manner in accordance with these regulations and the requirements of the Administrative Procedure Act. The presiding officer shall have the power to administer oaths and affirmations; to request the member of an advisory committee designated as provided by section 408 (d) (5) to testify with respect to the report and recommendations of the committee; to rule upon offers of proof and admissibility of evidence; to receive relevant evidence; to examine witnesses; to regulate the course of the hearing; to hold conferences for the simplification of the issues, and to dispose of procedural requests; but he shall not have power to decide any motion that involves final determination of the merits of the proceeding.

§ 120.16 *Parties; burden of proof; appearances.* At the hearing, the person whose objections raised the issues to be determined shall be, within the meaning of section 7 (c) of the Administrative Procedure Act, the proponent of the order sought, and accordingly shall have the burden of proof. Any interested person shall be given an opportunity to appear at the hearing, either in person or by his authorized representative, and to be heard with respect to matters relevant to the issues raised by the objections. Any interested person who desires to be heard at the hearing in person or through a representative shall, within the time specified in the notice of hearing, file with the presiding officer a written notice of appearance setting forth his name, address, and employment. If such person desires to be heard through a representative, such person or such representative shall file with the presiding officer a written appearance setting forth the name, address, and employment of such person. Any person or representative shall state with particularity in the appearance his interest in the proceedings and shall set forth the specific provisions of the regulations concerning which objections have been made on which such person desires to be heard. The appearance shall also set forth with particularity the position to be taken concerning the objections on which he wishes to be heard. No person shall be heard if he failed to file his appearance within the time prescribed in the absence of a clear showing of good cause why the appearance was not filed. All present at the hearing shall conform to all reasonable standards of orderly and ethical conduct.

§ 120.17 *Prehearing and other conferences.* (a) The presiding officer, on his own motion, or on the motion of any party or his representative, may direct all parties or their representatives to appear at a specified time and place for a conference to consider:

(1) The simplification of the issues.

(2) The possibility of obtaining stipulations, admissions of facts and documents.

(3) The limitation of the number of expert witnesses.

(4) The scheduling of witnesses to be called.

(5) The advance submission of all documentary evidence.

(6) Such other matters as may aid in the disposition of the proceeding.

The presiding officer shall make an order which recites the action taken at the conference, the agreements made by the parties or their representatives, and the schedule of witnesses, and which limits the issues for hearing to those not disposed of by admissions or agreements. Such order shall control the subsequent course of the proceeding unless modified for good cause by subsequent order.

(b) The presiding officer may also direct all parties and their representatives to appear at conferences at any time during the hearing with a view to simplification, clarification, or shortening of the hearing.

§ 120.18 *Submission of documentary evidence in advance.* (a) All documentary evidence to be offered at the hearing shall be submitted to the presiding officer and to the parties sufficiently in advance of the offer of such documentary evidence for introduction into the record to permit study and preparation of cross-examination and rebuttal evidence.

(b) The presiding officer, after consultation with the parties at a conference called in accordance with § 120.17, shall make an order specifying the time at which documentary evidence shall be submitted. He shall also specify in his order the time within which objection to the authenticity of such documents must be made to comply with paragraph (d) of this section.

(c) Documentary evidence not submitted in advance in accordance with the requirements of paragraphs (a) and (b) of this section shall not be received in evidence in the absence of a clear showing that the offering party had good cause for his failure to produce the evidence sooner.

(d) The authenticity of all documents submitted in advance shall be deemed admitted unless written objection thereto is filed with the presiding officer upon notice to the other parties within the time specified by the presiding officer in accordance with paragraph (b) of this section, except that a party will be permitted to challenge such authenticity at a later time upon a clear showing of good cause for failure to have filed such written objection.

§ 120.19 *Excerpts from documentary evidence.* When portions only of a document are to be relied upon, the offering party shall prepare the pertinent excerpts, adequately identified, and shall supply copies of such excerpts, together with a statement indicating the purpose for which such materials will be offered, to the presiding officer and to the other parties. Only the excerpts, so prepared and submitted, shall be received in the record. However, the whole of the original document should be made available for examination and for use by opposing counsel for purposes of cross-examination.

§ 120.20 *Submission and receipt of evidence.* (a) Each witness shall, before proceeding to testify, be sworn or make affirmation.

(b) When necessary to prevent undue prolongation of the hearing, the presiding officer may limit the number of times any witness may testify, the repetitious examination and cross-examination of witnesses, or the amount of corroborative or cumulative evidence.

(c) The presiding officer shall admit only evidence which is relevant, material, and not unduly repetitious.

(d) Opinion evidence shall be admitted when the presiding officer is satisfied that the witness is properly qualified.

(e) The presiding officer shall file as exhibits the FEDERAL REGISTER promulgating the regulation to which objections were taken and any report, recommendations, underlying data, and reasons that were certified to the Secretary by an advisory committee pursuant to section 408 (d) (3). The report, recommendations, underlying data, and reasons shall be subject to section 7 (c) of the Administrative Procedure Act. All documents constituting the record accumulated up to the start of the hearing shall be open for inspection by interested persons during office hours in the office of the hearing clerk of the Department.

(f) The member of an advisory committee, if any, designated to testify, or any member requested to testify by the petitioner, the Department, or the presiding officer, or who upon his own initiative requests to be heard, shall appear and testify with respect to the report, recommendations, underlying data, and reasons of the committee. The designated member shall receive per diem and travel and subsistence expenses when incurred, as though he were attending a meeting of the advisory committee.

(g) If any person objects to the admission or rejection of any evidence or to other limitation of the scope of any examination or cross-examination, he shall state briefly the grounds for such objection, and the transcript shall not include extended argument or debate thereon except as ordered by the presiding officer. A ruling of the presiding officer on any such objection shall be a part of the transcript, together with such offer of proof as has been made.

§ 120.21 *Transcript of the testimony.* Testimony given at a hearing shall be reported verbatim. All written statements, charts, tabulations, and similar data offered in evidence at the hearing shall be marked for identification and, upon a showing satisfactory to the presiding officer of their authenticity, relevancy, and materiality, shall be received in evidence subject to the Administrative Procedure Act (sec. 7 (c), 60 Stat. 238; 5 U. S. C. 1006 (c)). Exhibits shall, if practicable, be submitted in quintuplicate. In case the required number of copies are not made available, the presiding officer shall exercise his discretion as to whether said exhibit shall be read in evidence or whether additional copies shall be required to be submitted within a time to be specified by the presiding officer. Where the testimony of a witness refers to a statute or to a report or document, the presiding officer shall, after inquiry relating to the identification of such statute, report, or document, determine whether the same shall be produced at the hearing and physically be made a part of the evidence by reference.

Where relevant and material matter offered in evidence is embraced in a report or document containing immaterial and irrelevant matter, such immaterial and irrelevant matter shall be excluded and shall be segregated insofar as practicable, subject to the direction of the presiding officer.

§ 120.22 *Oral and written arguments.* (a) Unless the presiding officer issues an announcement at the hearing authorizing oral argument before him, it shall not be permitted.

(b) The presiding officer shall announce at the hearing a reasonable period within which interested persons may file written arguments based solely upon the evidence received at the hearing, citing the pages of the transcript of the testimony or properly identified exhibits where such evidence occurs.

§ 120.23 *Indexing of record.* (a) Whenever it appears to the presiding officer that the record of hearing will be of such length that an index to the record will permit a more orderly presentation of the evidence and reduce delay, the presiding officer shall require counsel for the parties to prepare a daily topical index which will be available to the presiding officer and all parties. Preparation of such an index shall be apportioned among all counsel present in such manner as appears just and proper in the circumstances.

(b) The index should include each topic of testimony upon which evidence is taken, the name of each witness testifying upon the topic, the page of the record at which each portion of his testimony appeared, and the number of each exhibit relating to the topic. The index should also contain the name of each witness, followed by the topics upon which he testified and the page of the record at which such testimony appears.

§ 120.24 *Certification of record.* At the close of the hearing, the presiding officer shall afford interested persons a short time (not longer than 1 week, except in unusual cases) in which to point out errors that may have been made in transcribing the testimony. The presiding officer shall promptly thereafter order such corrections made as in his judgment are required to make the transcript conform to the testimony, and he shall certify the transcript of testimony and the exhibits to the Comsioner.

§ 120.25 *Filing the record of the hearing.* As soon as practicable after the close of the hearing, the complete record of the hearing shall be filed in the office of the Hearing Clerk. The record shall include the transcript of the testimony, and exhibits, and any written arguments that may have been filed.

§ 120.26 *Copies of the record of the hearing.* The Department will make provisions for a stenographic record of the testimony and for such copies of the transcript thereof as it requires for its own purposes. Any person desiring a copy of the record of the hearing or of any part thereof shall be entitled to the same upon payment of the costs thereof.

§ 120.27 *Proposed order.* As soon as practicable after the time for filing written arguments has ended the Commissioner shall prepare and cause to be published in the Federal Register a proposed order which shall incorporate findings of fact, recommend decisions on the objections which were the subject of the hearing and tentative regulations. The proposed order shall specify a reasonable time, ordinarily not to exceed 30 days, within which any interested person may file exceptions. The exceptions shall point out with particularity the alleged errors in said proposed order and shall contain a specific reference to the pages of the transcript of the testimony or to the exhibits on which each exception is based. Such exceptions may be accompanied by a memorandum brief.

§ 120.28 *Final order.* As soon as practicable after the time for filing exceptions has passed, the record and the exceptions shall be presented to the Secretary and he shall cause to be published in the Fedearl Register his final order promulgating the regulation.

ADOPTION OF TOLERANCE ON INITIATIVE OF SECRETARY OR ON REQUEST OF INTERESTED PERSONS; JUDICIAL REVIEW; TEMPORARY TOLERANCES; AMENDMENT AND REPEAL OF TOLERANCES; FEES

§ 120.29 *Adoption of tolerance on initiative of Secretary or on request of an interested person.* (a) Upon the request of an interested person (other than a person who has registered or who has submitted an application for the registration of an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act (7 U. S. C. 135)) furnishing reasonable grounds therefor, and upon advance deposit to cover fees as prescribed in § 120.33, the Commissioner may propose the issuance of a regulation establishing a tolerance for a pesticide chemical or exempting it from the necessity of a tolerance. Reasonable grounds shall include an explanation showing wherein the person has a substantial interest in such a tolerance or exemption from tolerance; information, if available, as to why registrant of the pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act has not petitioned for a tolerance or exemption from a tolerance; and adequate data on subjects outlined in clauses (A), (B), (C), (D), (E), and (F) of section 408 (d) (1) of the Federal Food, Drug, and Cosmetic Act. If the Commissioner concludes upon studying the request that it does not warrant a proposal for the issuance of a regulation, he shall so inform the person making the request and state the reasons for his decision.

(b) The notice of the proposal shall show whether it is made on the initiative of the Commissioner or at the request of an interested person, naming such person.

(c) If within 30 days after publication of the proposal a person who has registered, or who has submitted an application for registration of an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act containing the pesticide chemical named in the proposal, requests in writing that the proposal be referred to an advisory committee and makes advance deposit as provided by § 120.33 (i) (3), the Commissioner shall appoint a committee as provided in § 120.11 and refer the proposal and relevant data to such committee. The Department and the committee shall proceed as prescribed in section 408 and this part.

(d) If further advance deposits are not made upon request of the Commissioner, as provided in § 120.33 (i) (3), the request for referral of the petition to an advisory committee shall be considered withdrawn, and a tolerance shall be established within 90 days from the date on which the Commissioner requested the further advance deposit.

§ 120.30 *Judicial review.* (a) The Secretary of Health, Education, and Welfare hereby designates the Assistant General Counsel for Food and Drugs of the Department of Health, Education, and Welfare as the officer upon whom copy of petition for judicial review shall be served. Such officer shall be responsible for filing in the court a transcript of proceedings and the record on which the order of the Secretary of Health, Education, and Welfare is based. The transcript and record shall be certified by the Secretary.

(b) Before forwarding the transcript and record to the court the Department shall advise the petitioner of costs of preparing it and as soon as payment to cover fees is made shall forward the transcript of proceeding and record to the court.

§ 120.31 *Temporary tolerances.* (a) A temporary tolerance (or exemption from a tolerance) established under authority of section 408 (j) of the act shall be deemed to be a tolerance (or exemption from the requirement of a tolerance) for the purposes of section 408 (a) (1), or (2) of the act.

(b) (1) A request for a temporary tolerance or a temporary exemption from a tolerance by a person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act shall be accompanied by a copy of such experimental permit, such data as are available on subjects outlined in clauses (A), (B), (C), (D), (E), (F) and (G) of section 408 (d) (1), and an advance deposit to cover fees as provided in § 120.33 (d).

(2) Before an experimental permit has been obtained, the Pesticide Branch upon request of the Department of Agriculture or a person who proposes to apply for an experimental permit will consider available data and discuss its adequacy for the purpose of justifying a tolerance or exemption from a tolerance.

(c) A notice of the issuance of a temporary tolerance outlining any restrictions as to use of the chemical imposed under the experimental permit under the Federal Insecticide, Fungicide, and Rodenticide Act may be published in the Federal Register if the Commissioner deems such publication desirable.

(d) A temporary tolerance or exemption from a tolerance may be issued for a period designed to allow the orderly marketing of the raw agricultural commodities produced while testing a pesticide chemical under an experimental permit issued under authority of the Federal Insecticide, Fungicide, and Rodenticide Act when the Commissioner concludes that the public health can be adequately protected during such marketing. A temporary tolerance or exemption from a tolerance may be revoked if the experimental permit is revoked, or may be revoked at any time if it develops that the application for a temporary tolerance contains a misstatement of a material fact or that new scientific data or experience with the pesticide chemical indicates that it may be hazardous to the public health.

§ 120.32 *Procedure for amending and repealing tolerances or exemptions from tolerances.* (a) The Commissioner on his own initiative or on request from an interested person furnishing reasonable grounds therefor, may propose the issuance of a regulation amending or repealing a tolerance for a pesticide chemical on raw agricultural commodities or granting or repealing an exemption from tolerance for such chemical. Requests for such amendment or repeal shall be made in writing and accompanied by an advance deposit to cover fees as provided in § 120.33 (d).

(b) Reasonable grounds shall include an explanation showing wherein the person has a substantial interest in such tolerance or exemption from tolerance and an assertion of facts (supported by data if available) showing that new uses for the pesticide chemical have been developed or old uses abandoned, that new data are available as to toxicity of the chemical, or that experience with the application of the tolerance or exemption from tolerance may justify its amendment or repeal. Evidence that a person has registered or has submitted an application for the registration of an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act will be regarded as evidence that he has a substantial interest in a tolerance or exemption from the requirement of a tolerance for a pesticide chemical that consists in whole or in part of the economic poison. New data should be furnished in the form specified in § 120.7 (b) for submitting petitions.

(c) The notice announcing the proposal to amend or repeal a regulation shall show whether the proposal was made on the initiative of the Commissioner or at the request of an interested person, naming such person. From this point the proceedings shall be the same as prescribed by section 408 (e), beginning with the second sentence of that paragraph, and the regulations applicable to section 408 (d), (e), (f), and (g).

§ 120.33 *Fees.* (a) Except as noted in paragraphs (b) and (c) of this section, each petition or request for the establishment of a tolerance shall be accompanied by a deposit of $1,000, plus $100 for each raw agricultural commodity more than nine on which the establishment of a tolerance is requested.

(b) Except as noted in paragraph (c) of this section, a petition requesting two or more numerical tolerance levels shall be accompanied by a deposit of $1,500, plus $100 for each raw agricultural commodity more than 14 on which the establishment of a tolerance is requested.

(c) Each petition or request for the establishment of a tolerance at a lower numerical level or levels than a tolerance already established for the same pesticide chemical, or for the establishment of a tolerance on additional raw agricultural commodities at the same numerical level as a tolerance already established for the same pesticide chemical, shall be accompanied by a deposit of $100, plus $100 for each raw agricultural commodity on which a tolerance is requested.

(d) Each petition or request for an exemption or a temporary exemption from the requirement of a tolerance, a temporary tolerance, or the amendment or repeal of a tolerance or exemption shall be accompanied by a deposit of $1,000, unless it meets the requirements of subparagraph (1) or (2) of this paragraph.

(1) Such deposit is not required when, in connection with the change sought under this paragraph, a petition or request is filed for the establishment of new tolerances to take the place of those sought to be amended or repealed and a deposit is made as required by paragraph (a) or (b) of this section.

(2) A request for a temporary tolerance for a pesticide chemical which has a tolerance for other uses at the same numerical level shall be accompanied by a deposit of $100 for clerical handling and initial administrative review, plus $100 for each raw agricultural commodity on which the temporary tolerance is sought.

(e) If a petition or a request proposing the issuance of a regulation is not accepted for filing or processing because it is technically incomplete, the deposit, less a $100 fee for clerical handling and initial administrative review, shall be returned unless the petitioner indicates that he wishes to submit a supplement, in which case the deposit will be held by the Commissioner, and the supplement shall be accompanied by a nonreturnable fee of $100.

(f) When a petition is withdrawn after filing and resubmitted within 6 months, it shall be accompanied by a deposit of $300, or by a deposit equal to the one originally submitted, whichever is smaller. If resubmitted after 6 months, it shall be accompanied by the deposit that would be required if it were being submitted for the first time.

(g) After a petition has been filed, any additional information or data submitted in support of it (i. e., any substantive amendment) shall be accompanied by a deposit of $300 or by a deposit equal to the one originally submitted, whichever is smaller.

(h) Objections under section 408 (d) (5) of the act shall be accompanied by a filing fee of $250.00.

(i) (1) In the event of a referral of a petition or proposal under this section to an advisory committee, the costs shall be borne by the person who requests the referral of the data to the advisory committee.

(2) Cost of the advisory committee, including expenses of the secretariat, will not exceed $75.00 per member per day plus cost of duplicating documents referred to the committee, plus necessary traveling and subsistence expenses of the members while they are serving away from their places of residence.

(3) An advance deposit shall be made in the amount of $2,500 to cover the costs. Further advance deposits of $2,500 each shall be made upon request of the Commissioner when necessary to prevent arrears in the payment of such costs. Any deposits in excess of actual expenses will be refunded to the depositor.

(j) The person who files a petition for judicial review of an order under section 408 (d) (5) or (e) of the act shall pay the costs of preparing a transcript of the proceedings and the record on which the order is based.

(k) All deposits and fees required by the regulations in this part shall be paid by money order, bank draft, or certified check drawn to the order of the Food and Drug Administration, collectible at par at Washington, D. C. All deposits and fees shall be forwarded to the Food and Drug Administration, Department of Health, Education, and Welfare, Washington 25, D. C., whereupon after making appropriate record thereof they will be transmitted to the Treasurer of the United States, for deposit to the special account "Certification and Inspection Services, Food and Drug Administration."

(l) The Commissioner may waive or refund such fees in whole or in part when in his judgment such action will promote the public interest.

(m) Any person who believes that payment of these fees will work a hardship on him may petition the Commissioner to waive or refund the fees.

TOLERANCES FOR RESIDUES

§ 120.101 *Specific tolerances for pesticide residues in or on fresh fruits and vegetables.* (a) (1) This section designates the poisonous or deleterious substances that, for the purposes of section 406 of the Federal Food, Drug, and Cosmetic Act, are found to be required in the production of the fresh fruits or vegetables named in paragraph (e) of this section. The tolerances established for such substances apply only to residues resulting from their application prior to harvest. A tolerance in terms of parts by weight for the poisonous or deleterious substance, or poisonous or deleterious residue resulting from its addition, to 1 million parts by weight of the fruit or vegetable is set forth after the name of each of the required substances.

(2) For the purposes of this section, the following substances are not considered as poisonous or deleterious substances: Sulfur, lime, lime-sulfur.

(b) The poisonous and deleterious substances for which tolerances are established by this section are named by their common names wherever practicable, otherwise by their chemical names or by names assigned to them by the United States Department of Agriculture. For the purposes of this section, the substances for which common, group, or Department of Agriculture names are used are as follows:

Name	Refers to—
Aldrin	A product consisting of 95 percent of the compound 1,2,3,4,10,10-hexachloro-1,4,4a,5,8,8a-hexahydro-1,4,5,8-dimethanonaphthalene and 5 percent chlorinated hydrocarbons.
Chlordane	1,2,4,5,6,7,8,8-octachloro-2,3,3a,4,7,7a-hexahydro-4,7-methanoindene.
DDT	A product consisting of a complex mixture of 1,1,1-trichloro-2,2-bis (parachlorophenyl) ethane and 1,1,1,-trichloro-2-(orthochlorophenyl)-2-(parachlorophenyl) ethane.
Dieldrin	1,2,3,4,10,10-hexachloro-6,7-epoxy-1,4,4a,5,6,7,8,8a-octahydro-1,4,5,8-dimethanonaphthalene.
EPN	O-ethyl O-paranitrophenyl benezene thiophosphonate.
Ferbam	Ferric dimethyl dithiocarbamate.
Fluorine compounds	Cryolite, synthetic cryolite (sodium aluminum fluoride).
Heptachlor	1,4,5,6,7,8,8-heptachloro-3a,4,7,7a-tetrahydro-4,7-methanoindene.
Lindane	The gamma isomer of benzene hexachloride.
Methoxychlor	2,2-bis(paramethoxyphenyl)-1,1,1-trichloroethane.
Nicotine compounds	Nicotine sulfate and other salts of nicotine; nicotine as the alkaloid.
Parathion	O,O-diethyl-O-paranitrophenyl thiophosphate.
TDE	1,1-dichloro-2,2-bis(parachlorophenyl) ethane.
TEPP	Tetraethyl pyrophosphate.
Toxaphene	Chlorinated camphene.
Zineb	Zinc ethylene bisdithiocarbamate.
Ziram	Zinc dimethyl dithiocarbamate.

(c) (1) Where a tolerance is established by this section for parathion, the methyl homologue of parathion may replace all or part of the parathion permitted by such tolerance.

(2) For the purposes of this section, where a tolerance of 5 parts per million for benzene hexachloride is set, it shall be deemed applicable to commercial benzene hexachloride, which is a mixture of several isomers. If the gamma isomer, known as lindane, is used exclusively of other isomers, the tolerance shall be 10 parts per million.

(3) For the purposes of this section, where a tolerance is established for more than one pesticide containing arsenic, found on a fruit or vegetable, the total amount of such pesticides shall not yield more than 3.5 parts per million of As_2O_3 on the fruit or vegetable to which added.

(4) For the purposes of this section, in those cases where the same numerical tolerance is established for more than one metallic dithiocarbamate (ferbam, maneb, ziram, or zineb) on a raw agricultural commodity, the total amount of metallic dithiocarbamate residues on such commodity, when calculated as zinc ethylenebisdithiocarbamate, shall not exceed the tolerance established for each metallic dithiocarbamate.

(5) For the purposes of this section:

(i) The following compounds are members of the class of chlorinated hydrocarbons:

Aldrin.
Benzene hexachloride.
Chlordane.
Chlorinated camphene (toxaphene).
Chlorobenzilate (ethyl 4,4′-dichlorobenzilate.
DDD (TDE or Rhothane).
DDT.
2,4-Dichlorophenoxy acetic acid.
Dieldrin.
Heptachlor.
Lindane.
Methoxychlor.
SES (sodium 2,4-dichlorophenoxyethyl sulfate).
Sulphenone (p-chlorophenyl phenyl sulfone).

(ii) The following compounds are members of the class of organic phosphates:

EPN
Malathion.
Methyl homologue of parathion (Metacide).
Parathion.
Systox (O,O-diethyl-2-ethylmercaptoethyl) thiosphate, a mixture of the thiono and thiol isomers).

(iii) The following compounds are members of the class of dinitro compounds: Dinitro-O-cyclohexylphenol; dicyclohexylamine salt of dinitro-O-cyclohexylphenol.

(iv) Except as noted in subdivisions (v) and (vi) of this subparagraph, where residues from two or more chemicals in the same class are present on a fruit or vegetable the tolerance for the total of such residues shall be the same as that for the chemicals having the lowest numerical tolerance in this class.

(v) Where residues from two or more chemicals in the same class are present in a fruit or vegetable and there are available methods that permit quantitative determination of each residue, the quantity of combined residues that are within the tolerance may be determined as follows:

(a) Determine the quantity of each residue present.

(b) Divide the quantity of each residue by the tolerance that would apply if it occurred alone, and multiply by 100 to determine the percentage of the permitted amount of residue present.

(c) Add the percentages so obtained for all residues present.

(d) The sum of the percentages shall not exceed 100 percent.

(vi) Where residues from two or more chemicals in the same class are present on a fruit or vegetable and there are available methods that permit quantitative determination of one or more, but not all, of the residues, the amounts of such residues as may be determinable shall be deducted from the total amount of residues present and the remainder shall have the same tolerance as that for the chemical having the lowest numerical tolerance in that class. The quantity of combined residues that are within the tolerance may be determined as follows:

(a) Determine the quantity of each determinable residue present.

(b) Deduct the amounts of such residues from the total amount of residue present and consider the remainder to have the same tolerance as that for the chemical having the lowest numerical tolerance in that class.

(c) Divide the quantity of each determinable residue by the tolerance that would apply if it occurred alone and the quantity of the remaining residue by the tolerance for the chemical having the lowest numerical tolerance in that class and multiply by 100 to determine the percentage of the permitted amount of residue present.

(d) Add the percentages so obtained for all residues present.

(e) The sum of the percentages shall not exceed 100 percent.

(d) Residues of the following poisonous or deleterious substances should not remain on fruits or vegetables as prepared for market:

Calcium cyanide.
Dinitro-O-sec. butylphenol.
Dinitro-O-cresol.
Hexaethyl tetraphosphate.
Tetraethyl pyrophosphate.
Hydrocyanic acid.
Mercury-containing compounds.
Selenium and selenium compounds.

(e) Each subparagraph of this paragraph lists, under the names of the fresh fruits and vegetables specified, the substances found to be required in their production and the tolerances for the residues of these substances remaining in or on such fresh fruits or vegetables. The abbreviation "p. p. m." means parts per million.

FRUITS

(1) *Apples, pears, and quinces.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
2,4-Dichlorophenoxy acetic acid	5 p. p. m.
Dicyclohexylamine salt of dinitro-O-cyclohexylphenol.	1 p. p. m.
Dieldrin	0.1 p. p. m.
EPN	3 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
2-Heptadecyl glyoxalidine	5 p. p. m.
Lead arsenate	7 p. p. m. of combined lead.
Methoxychlor	14 p. p. m.
Naphthalene acetic acid	1 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.

FRUITS—continued

(1) *Apples, pears, and quinces*—Continued

Pesticide	*Tolerance*
Phenothiazine	7 p. p. m.
TDE	7 p. p. m.
Toxaphene	7 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(2) *Apricots.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
Dicyclohexylamine salt of dinitro-*O*-cyclohexylphenol.	1 p. p. m.
Dieldrin	0.1 p. p. m.
EPN	3 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Lead arsenate	7 p. p. m. of combined lead.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
TDE	7 p. p. m.
Toxaphene	7 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(3) *Avocados.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
DDT	7 p. p. m.
Lead arsenate	7 p. p. m. of combined lead.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.

(4) *Blackberries.* For tolerances established for pesticide residues on blackberries, see subparagraph (27) of this paragraph.

(5) *Blueberries* (*huckleberries*).

Pesticide	*Tolerance*
Calcium arsenate	3.5 p. p. m. of combined As_2O_3.
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Lead arsenate	7 p. p. m. of combined lead.
Methoxychlor	14 p. p. m.
Parathion	1 p. p. m.
TDE	7 p. p. m.
Ziram	7 p. p. m.

(6) *Cherries.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
Dicyclohexylamine salt of dinitro-*O*-cyclohexylphenol.	1 p. p. m.
Dieldrin	0.1 p. p. m.
EPN	3 p. p. m.

FRUITS—continued

(6) *Cherries*—Continued

Pesticide	*Tolerance*
Ferbam	7 p. p. m.
2-Heptadecyl glyoxalidine	5 p. p. m.
Lead arsenate	7 p. p. m. of combined lead.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
TDE	7 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(7) *Citrus fruits* (*grapefruit, lemons, limes, oranges, tangerines*).

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
2,4,Dichlorophenoxy acetic acid	5 p. p. m.
Dicyclohexylamine salt of dinitro-*O*-cyclohexylphenol.	1 p. p. m.
Dinitro-*O*-cyclohexylphenol	1 p. p. m.
EPN	3 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Lead arsenate	1 p. p. m. of combined lead.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
Tartar emetic	3.5 p. p. m. of combined antimony trioxide.
TDE	7 p. p. m.
Toxaphene	7 p. p. m.
Zineb	7 p. p. m.

(8) *Cranberries.*

Pesticide	*Tolerance*
DDT	7 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Lead arsenate	7 p. p. m. of combined lead.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(9) *Currants.*

Pesticide	*Tolerance*
DDT	7 p. p. m.
Ferbam	7 p. p. m.
Lead arsenate	7 p. p. m. of combined lead.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
Zineb	7 p. p. m.

(10) *Dates.*

Pesticide	*Tolerance*
Ferbam	7 p. p. m.
Parathion	1 p. p. m.

(11) *Figs.*

Pesticide	*Tolerance*
Parathion	1 p. p. m.

FRUITS—continued

(12) *Gooseberries.*

Pesticide	*Tolerance*
DDT	7 p. p. m.
Ferbam	7 p. p. m.
Lead arsenate	7 p. p. m. of combined lead.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(13) *Grapefruit.* For tolerances established for pesticide residues on grapefruit, see subparagraph (7) of this paragraph.

(14) *Grapes.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
Dicyclohexylamine salt of dinitro-*O*-cyclohexylphenol.	1 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Lead arsenate	7 p. p. m. of combined lead.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
Sodium arsenate	3.5 p. p. m. of combined As_2O_3.
Tartar emetic	3.5 p. p. m. of combined antimony trioxide.
TDE	7 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(15) *Guavas.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
DDT	7 p. p. m.
Ferbam	7 p. p. m.
Parathion	1 p. p. m.
Zineb	7 p. p. m.

(16) *Lemons.* For tolerances established for pesticide residues on lemons, see subparagraph (7) of this paragraph.

(17) *Loganberries.* For tolerances established for pesticide residues on loganberries, see subparagraph (27) of this paragraph.

(18) *Mangoes.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
DDT	7 p. p. m.
Ferbam	7 p. p. m.
Lead arsenate	7 p. p. m. of combined lead.
Parathion	1 p. p. m.

(19) *Nectarines.* For tolerances established for pesticide residues on nectarines, see subparagraph (22) of this paragraph.

(20) *Oranges.* For tolerances established for pesticide residues on oranges, see subparagraph (7) of this paragraph.

(21) *Papayas.*

Pesticide	*Tolerance*
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
Ferbam	7 p. p. m.

FRUITS—continued

(22) *Peaches and nectarines.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
Dicyclohexylamine salt of dinitro-*O*-cyclohexylphenol.	1 p. p. m.
Dieldrin	0.1 p. p. m.
EPN	3 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Lead arsenate	7 p. p. m. of combined lead.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
TDE	7 p. p. m.
Toxaphene	7 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(23) *Pears.* For tolerances established for pesticide residues on pears, see subparagraph (1) of this paragraph.

(24) *Pinapples.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
EPN	3 p. p. m.
Methoxychlor	14 p. p. m.
Parathion	1 p. p. m.

(25) *Plums (fresh prunes).*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
Dicyclohexylamine salt of dinitro-*O*-cyclohexylphenol.	1 p. p. m.
EPN	3 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Lead arsenate	7 p. p. m. of combined lead.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
TDE	7 p. p. m.
Zineb	7 p. p. m.

(26) *Quinces.* For tolerances established for pesticide residues on quinces, see subparagraph (1) of this paragraph.

(27) *Raspberries, blackberries, loganberries, and related berries.*

Pesticide	*Tolerance*
Calcium arsenate	3.5 p. p. m. of combined As_2O_3.
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
Dicyclohexylamine salt of dinitro-*O*-cyclohexylphenol.	1 p. p. m.
EPN	3 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.

FRUITS—continued

(27) *Raspberries, blackberries, loganberries, and related berries*—Continued

Pesticide	*Tolerance*
2-Heptadecyl glyoxalidine	5 p. p. m.
Lead arsenate	7 p. p. m. of combined lead.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
TDE	7 p. p. m.
Toxaphene	7 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(28) *Rhubarb.*

Pesticide	*Tolerance*
DDT	7 p. p. m.

(29) *Strawberries.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
Calcium arsenate	3.5 p. p. m. of combined As_2O_3.
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
Dicyclohexylamine salt of dinitro-O-cyclohexylphenol.	1 p. p. m.
EPN	3 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Lead arsenate	7 p. p. m. of combined lead.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
TDE	7 p. p. m.
Toxaphene	7 p. p. m.
Zineb	7 p. p. m.

(30) *Tangerines.* For tolerances established for pesticide residues on tangerines, see subparagraph (7) of this paragraph.

VEGETABLES

(31) *Artichokes.*

Pesticide	*Tolerance*
DDT	7 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.

(32) *Asparagus.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
Calcium arsenate	3.5 p. p. m. of combined As_2O_3.
DDT	7 p. p. m.
Ferbam	7 p. p. m.
Lead arsenate	7 p. p. m. of combined lead.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.

(33) *Beans, green beans, snap beans, lima beans, and black-eyed peas.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
Calcium arsenate	3.5 p. p. m. of combined As_2O_3.
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
Dicyclohexylamine salt of dinitro-O-cyclohexylphenol.	1 p. p. m.

VEGETABLES—continued

(33) *Beans, green beans, snap beans, lima beans, and black-eyed peas*—Continued

Pesticide	*Tolerance*
EPN	3 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Magnesium arsenate	3.5 p. p. m. of combined As_2O_3.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
TDE	7 p. p. m.
Toxaphene	7 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(34) *Beets (with or without tops) or beet greens alone.*

Pesticide	*Tolerance*
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
EPN	3 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(35) *Black-eyed peas.* For tolerances established for pesticide residues on black-eyed peas, see subparagraph (33) of this paragraph.

(36) *Broccoli.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
Calcium arsenate	3.5 p. p. m. of combined As_2O_3.
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
TDE	7 p. p. m.
Toxaphene	7 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(37) *Brussels sprouts.* For tolerances established for pesticide residues on brussels sprouts, see subparagraph (38) of this paragraph.

(38) *Cabbage, brussels sprouts, kohlrabi, cauliflower.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
Calcium arsenate	3.5 p. p. m. of combined As_2O_3.
Chlordane	0.3 p. p. m.
Copper arsenate	3.5 p. p. m. of combined As_2O_3.
DDT	7 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
TDE	7 p. p. m.
Toxaphene	7 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

VEGETABLES—continued

(39) *Carrots (with or without tops) or carrot tops.*

Pesticide	*Tolerance*
Calcium arsenate	3.5 p. p. m. of combined As_2O_3.
Chlordane	0.3 p. p. m.
Copper arsenate	3.5 p. p. m. of combined As_2O_3.
DDT	7 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Parathion	1 p. p. m.
TDE	7 p. p. m.
Toxaphene	7 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(40) *Cauliflower.* For tolerances established for pesticide residues on cauliflower, see subparagraph (38) of this paragraph.

(41) *Celery.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
Calcium arsenate	3.5 p. p. m. of combined As_2O_3.
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
Dicyclohexylamine salt of dinitro-O-cyclohexylphenol.	1 p. p. m.
Ferbam	7 p. p. m.
Lead arsenate	7 p. p. m. of combined lead.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
Toxaphene	7 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(42) *Collards.* For tolerances established for pesticide residues on collards, see subparagraph (47) of this paragraph.

(43) *Corn.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
Calcium arsenate	3.5 p. p. m. of combined As_2O_3.
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
EPN	3 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
TDE	7 p. p. m.
Toxaphene	7 p. p. m.
Zineb	7 p. p. m.

(44) *Cucumbers.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
Calcium arsenate	3.5 p. p. m. of combined As_2O_3.
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
TDE	7 p. p. m.
Toxaphene	7 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(45) *Eggplants.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
Calcium arsenate	3.5 p. p. m. of combined As_2O_3.
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Lead arsenate	7 p. p. m. of combined lead.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
TDE	7 p. p. m.
Toxaphene	7 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(46) *Endive and escarole.*

Pesticide	*Tolerance*
DDT	7 p. p. m.
Parathion	1 p. p. m.
Zineb	7 p. p. m.

(47) *Kale and collards.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
Calcium arsenate	3.5 p. p. m. of combined As_2O_3.
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(48) *Kohlrabi.* For tolerances established for pesticide residues on kohlrabi, see subparagraph (38) of this paragraph.

(49) *Lettuce.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
EPN	3 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
TDE	7 p. p. m.
Toxaphene	7 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

VEGETABLES—continued

(50) *Lima beans.* For tolerances established for pesticide residues on lima beans, see subparagraph (33) of this paragraph.

(51) *Melons, including cantaloupes, muskmelons, watermelons, and other melons.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
Calcium arsenate	3.5 p. p. m. of combined As_2O_3.
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
TDE	7 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(52) *Mushrooms.*

Pesticide	*Tolerance*
DDT	7 p. p. m.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.

(53) *Mustard greens.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
DDT	7 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
Zineb	7 p. p. m.

(54) *Okra.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
Toxaphene	7 p. p. m.

(55) *Onions.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
Chlordane	0.3 p. p. m.
Dieldrin	0.1 p. p. m.
DDT	7 p. p. m.
Ferbam	7 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
Tartar emetic	3.5 p. p. m. of combined antimony trioxide.
Toxaphene	7 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(56) *Parsley.*

Pesticide	*Tolerance*
Nicotine-containing compounds	2 p. p. m. of nicotine.
Zineb	7 p. p. m.

VEGETABLES—continued

(57) *Parsnips (with or without tops) or parsnip greens alone.*

Pesticide	*Tolerance*
DDT	7 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.

(58) *Peanuts.*

Pesticide	*Tolerance*
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Parathion	1 p. p. m.
Toxaphene	7 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(59) *Peas.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
TDE	7 p. p. m.
Toxaphene	7 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(60) *Peppers.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
Calcium arsenate	3.5 p. p. m. of combined As_2O_3.
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Lead arsenate	7 p. p. m. of combined lead.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
TDE	7 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(61) *Potatoes.* Tolerances are not needed for those pesticides applied only to the foliage of potatoes and that are not translocated to the tubers.

Pesticide	*Tolerance*
Aldrin	0.1 p. p. m.
Chlordane	0.3 p. p. m.
Heptachlor	0.1 p. p. m.

(62) *Pumpkins.*

Pesticide	*Tolerance*
Benzene hexachloride	5 p. p. m.
Calcium arsenate	3.5 p. p. m. of combined As_2O_3.
DDT	7 p. p. m.

VEGETABLES—continued

(62) *Pumpkins*—Continued

Pesticide	Tolerance
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
TDE	7 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(63) *Radishes (with or without tops) or radish tops.*

Pesticide	Tolerance
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
TDE	7 p. p. m.
Toxaphene	7 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(64) *Rutabagas (with or without tops) or rutabaga tops.* For tolerances established for pesticide residues on rutabagas, see subparagraph (71) of this paragraph.

(65) *Salsify.*

Pesticide	Tolerance
Zineb	7 p. p. m.

(66) *Spinach.*

Pesticide	Tolerance
Benzene hexachloride	5 p. p. m.
Calcium arsenate	3.5 p. p. m. of combined As_2O_3.
DDT	7 p. p. m.
EPN	3 p. p. m.
Ferbam	7 p. p. m.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
TDE	7 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(67) *Squash, summer squash.*

Pesticide	Tolerance
Benzene hexachloride	5 p. p. m.
Calcium arsenate	3.5 p. p. m. of combined As_2O_3.
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined fluorine.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
TDE	7 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(68) *Sweetpotatoes.* Tolerances are not needed for those pesticides applied only to foliage of sweetpotatoes and which are not translocated to the tubers.

Pesticide	Tolerance
Aldrin	0.1 p. p. m.

VEGETABLES—continued

(69) *Swiss chard.*

Pesticide	Tolerance
Benzene hexachloride	5 p. p. m.
DDT	7 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
TDE	7 p. p. m.
Zineb	7 p. p. m.

(70) *Tomatoes.*

Pesticide	Tolerance
Benzene hexachloride	5 p. p. m.
Calcium arsenate	3.5 p. p. m. of combined As_2O_3.
Chlordane	0.3 p. p. m.
Copper arsenate	3.5 p. p. m. of combined As_2O_3.
DDT	7 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined flourine.
Lead arsenate	7 p. p. m. of combined lead.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
TDE	7 p. p. m.
Toxaphene	7 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(71) *Turnips or rutabagas (with or without tops) or turnip greens or rutabaga tops.*

Pesticide	Tolerance
Calcium arsenate	3.5 p. p. m. of combined As_2O_3.
Chlordane	0.3 p. p. m.
DDT	7 p. p. m.
EPN	3 p. p. m.
Ferbam	7 p. p. m.
Fluorine compounds	7 p. p. m. of combined flourine.
Methoxychlor	14 p. p. m.
Nicotine-containing compounds	2 p. p. m. of nicotine.
Parathion	1 p. p. m.
TDE	7 p. p. m.
Zineb	7 p. p. m.
Ziram	7 p. p. m.

(f) In accordance with section 408 (k) of the Federal Food, Drug, and Cosmetic Act, these tolerances shall be deemed also tolerances under section 408.

§ 120.102 *Tolerances for residues of SES (sodium 2,4-dichlorophenoxyethyl sulfate).* The following tolerances are established for residues of SES (sodium 2,4-dichlorophenoxyethyl sulfate) in or on the raw agricultural commodities indicated:

(a) 6 parts per million in or on potatoes, peanuts, peanut hulls, peanut hay.

(b) 2 parts per million in or on asparagus, strawberries.

§ 120.103 *Tolerance for residues of captan.* A tolerance of 20 parts per million is established for residues of captan (*N*-trichloromethyl mercapto-4-cyclohexene-1,2-dicarboximide) in or on the raw agricultural commodities apples, apricots, cantaloups, cherries, cucumbers, eggplant, grapefruit, grapes, lemons, limes, mangoes, nectarines, oranges, peaches, pears, peppers, pineapple, plums, prunes, pumpkin, quinces, summer squash, strawberries, tangerines, tomatoes, watermelon, winter squash.

§ 120.104 *Extended tolerance for residues of heptachlor (1,4,5,6,7,8,8-heptachloro-3a,4,7,7a-tetrahydro-4,7-methanoindene).* The tolerance of 0.1 part per million for residues of heptachlor (§ 120.101 (e) (61); 20 F. R. 1507) is extended to include the following raw agricultural commodities: Alfalfa, clover, sweet clover; beets (including sugar beets;) cabbage, brussels sprouts, kohlrabi, cauliflower; corn; cotton; pasture and range grass; onions; peanuts; sugarcane; sweetpotatoes; turnips with tops and rutabagas (yellow turnips) without tops.

§ 120.105 *Tolerance for residues of Systox (O,O-diethyl-(2-ethylmercaptoethyl) thiophosphate, a mixture of the thiono and thiol isomers).* A tolerance of 0.75 part per million for residues of Systox (*O,O*-diethyl-(2-ethylmercaptoethyl) thiophosphate — a mixture of the thiono and thiol isomers) and derived anticholinesterase products as determined by in vitro cholinesterase inhibition of pooled human plasma, using technical Systox as a standard (this standard effects 50-percent inhibition of pooled human plasma cholinesterase at a concentration of 0.3±0.025 part per million in water as a medium) is established in or on the following raw agricultural commodities: Apples, broccoli, brussels sprouts, cabbage, cauliflower, muskmelons, oranges, pears, potatoes, strawberries, and walnuts.

§ 120.106 *Tolerance for residues of 3-(3,4-dichlorophenyl) 1,1-dimethylurea.* A tolerance of 1.0 part per million for residues of 3-(3,4-dichlorophenyl) 1,1-dimethylurea is established in or on the following raw agricultural commodities: Cottonseed, pineapple, and sugarcane.

§ 120.107 *Tolerances for residues of Aramite.* (a) A tolerance of 1 part per million is established for residues of Aramite (2-(*p-tert*-butylphenoxy)-isopropyl-2-chloroethyl sulfite) on the raw agricultural commodities apples, blueberries, cantaloups, celery, cucumbers, grapefruit, grapes, green beans, lemons, muskmelons, oranges, peaches, pears, plums, raspberries, strawberries, sweet corn (kernels) but not forage thereof, tomatoes, watermelons.

(b) A tolerance of zero is established for residues of Aramite in or on the raw agricultural commodities alfalfa and soybeans (whole plant).

§ 120.108 *Tolerance for residues of 3 - (p - chlorophenyl) -1,1-dimethylurea.* A tolerance of 1 part per million for residues of 3-(*p*-chlorophenyl)-1,1-dimethylurea is established in or on the following raw agricultural commodities: Asparagus, cottonseed, onions (dry bulbs only), pineapple, spinach, sugarcane.

§ 120.109 *Tolerances for residues of Chlorobenzilate (ethyl 4,4′-dichlorobenzilate).* A tolerance of 5 parts per million is established for residues of Chlorobenzilate (ethyl 4,4′-dichlorobenzilate) in or on each of the following raw agricultural commodities: Apples, cantaloups, lemons, oranges, and pears.

§ 120.110 *Tolerances for residues of maneb (manganese ethylenebisdithiocarbamate).* Tolerances for residues of maneb (manganese ethylenebisdithiocarbamate), calculated as zinc ethylenebisdithiocarbamate, are established as follows:

(a) 7 parts per million in or on apples, beans, carrots (with or without tops) or carrot tops, celery, cranberries, cucumbers, eggplant, figs, grapes, melons, onions, peaches, peppers, spinach, summer squash, tomatoes, and winter squash.

(b) 0.1 part per million in or on almonds and potatoes.

§ 120.111 *Tolerances for residues of malathion.* A tolerance of 8 parts per million is established for residues of malathion (*O,O*-dimethyl dithiophosphate of diethyl mercaptosuccinate) in or on the following raw agricultural commodities: Alfalfa, apples, apricots, avocados, beans, beets (including tops), blueberries, broccoli, brussels sprouts, cabbage, cauliflower, celery, cherries, clover, cranberries, cucumbers, dates, eggplants, grapes, kale, lettuce, mangoes, melons, mustard greens, onions (including green onions), passion fruit, peaches, peas, pears, peppers, pineapples, plums, potatoes, prunes, rutabagas, spinach, squash (both summer and winter squash), strawberries, tomatoes, turnips (including tops).

§ 120.112 *Tolerances for residues of Sulphenone (p-chlorophenyl phenyl sulfone).* A tolerance of 8 parts per million for residues of Sulphenone (*p*-chlorophenyl phenyl sulfone) is established in or on each of the following raw agricultural commodities: Apples, peaches, pears.

§ 120.113 *Exemption from the requirement of a tolerance for residues of allethrin.* (a) Allethrin (allyl homolog of cinerin I) is exempted from the requirement of a tolerance for residues when used before harvest in the production of beans, broccoli, brussels sprouts, cabbage, kale, cauliflower, collards, horseradish, kale, kohlrabi, lettuce, mushrooms, mustard greens, radish, rutabagas, turnips.

(b) Allethrin is not exempted from the requirement of a tolerance when used at time of or after harvest.

§ 120.114 *Tolerance for residues of ferbam.* A tolerance of 0.1 part per million is established for residues of ferbam (ferric dimethyldithiocarbamate), calculated as zinc ethylenebisdithiocarbamate, in or on almonds.

§ 120.115 *Tolerance for residues of zineb.* A tolerance of 7 parts per million is established for residues of zineb (zinc ethylenebisdithiocarbamate) in or on mushrooms.

§ 120.116 *Tolerances for residues of ziram.* (a) A tolerance of 7 parts per million is established for residues of ziram (zinc dimethyldithiocarbamate), calculated as zinc ethylenebisdithiocarbamate, in or on strawberries.

(b) A tolerance of 0.1 part per million is established for residues of ziram (zinc dimethyldithiocarbamate), calculated as zinc ethylenebisdithiocarbamate, in or on almonds and pecans.

§ 120.117 *Tolerance for residues of chloretetracycline.* A tolerance of 7 parts per million is established for residues of chloretetracycline in or on uncooked poultry. This tolerance level shall not be exceeded in any part of the poultry.

§ 120.118 *Tolerances for residues of Phygon (dichlone or 2,3-dichloro-1,4-naphthoquinone).* A tolerance of 3 parts per million is established for residues of Phygon (dichlone or 2,3-dichloro-1,4-naphthoquinone) in or on each of the following raw agricultural commodities: Celery, tomatoes.

§ 120.119 *Tolerances for residues of EPN (O-ethyl-O-p-nitrophenyl benzene thiophosphonate.* Tolerances for residues of EPN (O-ethyl-O-*p*-nitrophenyl benzene thiophosphonate) are established as follows:

(1) 3 parts per million in or on grapes, olives, sugar beets (but not sugar beet tops), tomatoes.

(2) 0.5 part per million in or on almonds, cottonseed, pecans, walnuts.

PART 125—LABEL STATEMENTS CONCERNING DIETARY PROPERTIES OF FOOD PURPORTING TO BE OR REPRESENTED FOR SPECIAL DIETARY USES

Sec.
125.1 Definitions and interpretations of terms.
125.2 General label statements.
125.3 Label statements relating to vitamins.
125.4 Label statements relating to minerals.
125.5 Label statements relating to infant food.
125.6 Label statements relating to certain food used in control of body weight or in dietary management with respect to disease.
125.7 Label statements relating to non-nutritive constituents.
125.8 Label statements relating to hypo-allergenic food.
125.9 Label statements relating to certain foods used as a means of regulating the intake of sodium in dietary management.

AUTHORITY: §§ 125.1 to 125.9 issued under sec. 701 (a), 52 Stat. 1055; 21 U. S. C. 371 (a). Interpret or apply sec. 403 (j), 52 Stat. 1047; 21 U. S. C. 343 (j).

§ 125.1 *Definitions and interpretations of terms.* (a) The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable also to such terms when used in the regulations in this part.

(b) Any requirement of the regulations in this part with respect to the quantity of vitamin A means the biologically measured activity of vitamin A and its precursors; but if any such precursor is sold as such or is added to a food the label shall designate such precursor by its common or usual name and not as vitamin A.

(c) Specification in the regulations in this part of a quantity of any vitamin, mineral, or other dietary property as a minimum daily requirement shall not be construed as a determination that such quantity is sufficient for the treatment of any disease resulting from a deficiency in such vitamin, mineral, or other property.

(d) For the purposes of the regulations in this part, the terms "infant," "child," and "adult" mean persons not more than 12 months old, more than 12 months but less than 12 years old, and 12 years or more old, respectively.

§ 125.2 *General label statements.* (a) If a food (including food to which any one or more of §§ 125.3 to 125.8, inclusive, is applicable) purports to be or is represented for any special dietary use by man, its label shall bear a statement of the dietary properties upon which such use is based in whole or in part. Such statement shall show the presence or absence of any substance, any alteration of the quantity or character of any constituent, and any other dietary property of such food upon which such use is so based.

(b) If a food (including food to which any one or more of §§ 125.3 to 125.8, inclusive, is applicable) purports to be or is represented for special dietary use by reason of its use for treating any disease resulting from a dietary deficiency in man, its label shall bear, in addition to the information required under paragraph (a) of this section, adequate directions for such use.

§ 125.3 *Label statements relating to vitamins.* (a) (1) If a food purports to be or is represented for special dietary use by man by reason of its vitamin property in respect of:

Vitamin A or its precursors,
Vitamin B_1 (thiamine),
Vitamin C (ascorbic acid),
Vitamin D, or
Riboflavin (vitamin B_2, vitamin G),

the label (except as provided in this paragraph, with respect to cow's milk and evaporated milk, and unless the exemption under subparagraph (3) of this paragraph applies) shall bear a statement of the proportion of the minimum daily requirement for such vitamin supplied by such food when consumed in a specified quantity during a period of one day. If such purported or represented special dietary use is for persons within two or more age groups for which minimum daily requirements are set forth in paragraph (b), such statement shall include such proportion for each such group; but if such use is for persons irrespective of age groups, such statement may be limited to the proportion of the minimum daily requirement set forth in paragraph (b) of this section for an adult. The quantity specified as above required shall be the quantity customarily or usually consumed during a period of one day, or a quantity reasonably suitable for and practicable of consumption within such period. When such proportion is a whole number and a fraction it may be expressed as the whole number and the fraction may be disregarded. The foregoing requirements of this paragraph shall not apply to cow's milk and evaporated milk which purport to be or are represented for special dietary use by reason of their content of vitamin D; but in the case of cow's milk in which the vitamin D content has been increased by any means, and in the case of evaporated milk with increased vitamin D content as prescribed in the definition and standard of identity for evaporated milk (§ 18.520 of this chapter), the label shall bear a statement of the number of U. S. P. units in a specified quantity of such milk or evaporated milk. In the case of cow's milk in which the vitamin D content is increased to less than 135 U. S. P. units to each quart, the label shall also bear a statement that additional vitamin D should be supplied from other sources.

(2) If a food purports to be or is represented for special dietary use by man by reason of its vitamin property in respect of any vitamin not listed in subparagraph (1) of this paragraph, the label shall bear a statement of the quantity of such vitamin in a specified quantity of such food. The quantity of food specified as required by this section, shall be the quantity customarily or usually consumed during a period of one day, or a quantity reasonably suitable for and practicable of consumption within such period. If the need in human nutrition for such vitamin has not been established, the label shall also bear the statement "The need for -------- in human nutrition has not been established," the blank to be filled in with the name of such vitamin.

(3) If a food purports to be or is represented for special dietary use by man by reason of its vitamin property, and any such use is for treating any disease resulting from a dietary deficiency of any vitamin, the label shall bear a statement of the quantity of such vitamin in a specified quantity of such food. If the represented special dietary use of such food is solely for treating any such disease, such food shall be exempt from the labeling requirements of subparagraphs (1) and (2) of this paragraph when otherwise applicable.

(4) Compliance with the provisions of subparagraphs (2) and (3) of this paragraph shall not be construed as relieving any food which purports to be or is represented for special dietary use by reason of its vitamin property from the application of section 403 (a) and 201 (n) of the act, as in the case where the need for such vitamin in human nutrition is not substantially supported by the opinion of experts qualified by scientific training and experience to determine such needs.

(b) For the purposes of the regulations in this section the following are minimum daily requirements:

(1) For vitamin A, 1,500 U. S. P. units for an infant, 3,000 U. S. P. units for a child, 4,000 U. S. P. units for an adult.

(2) For vitamin B_1 (thiamine), 0.25 milligram (83 U. S. P. units) for an infant, 0.5 milligram (167 U. S. P. units) for a child less than six years old, 0.75 milligram (250 U. S. P. units) for a child six or more years old, 1 milligram (333 U. S. P. units) for an adult.

(3) For vitamin C (ascorbic acid), 10 milligrams (200 U. S. P. units) for an infant, 20 milligrams (400 U. S. P. units) for a child, 30 milligrams (600 U. S. P. units) for an adult.

(4) For vitamin D, 400 U. S. P. units for an infant, child, or adult.

(5) For riboflavin (vitamin B_2, vitamin G), 0.5 milligram for an infant, 2.0 milligrams for an adult.

§ 125.4 *Label statements relating to minerals.* (a) (1) If a food purports to be or is represented for special dietary use by man by reason of its mineral property in respect of:

Calcium,
Phosphorus,
Iron, or
Iodine,

the label (except as provided in this section with respect to iodized salt, and unless the exemption under subparagraph (3) of this paragraph applies) shall bear a statement of the proportion of the minimum daily requirement for such element supplied by such food when consumed in a specified quantity during a period of one day. If such purported or represented special dietary use is for persons within two or more age groups or other groups having special dietary requirements, for which minimum daily requirements are set forth in paragraph (b) of this section, such statement shall include such proportion for each such group; but if such use is for persons irrespective of such groups, such statement may be limited to the proportion of the minimum daily requirement set forth in paragraph (b) of this section for an adult other than a pregnant or lactating woman. The quantity specified as above required shall be the quantity customarily or usually consumed during a period of one day, or a quantity reasonably suitable for and practicable of consumption within such period. When such proportion is a whole number and a fraction it may be expressed as the whole number and the fraction may be disregarded. The foregoing requirements of this paragraph shall not apply to iodized salt which purports to be or is represented for special dietary use by reason of its iodine content, if the label bears a statement of the quantity or proportion of iodine, or salt thereof, in the iodized salt and the quantity of iodine present therein is not more than 0.02 percent by weight.

(2) If a food purports to be or is represented for special dietary use by man by reason of its mineral property in respect of any element not listed in subparagraph (1) of this paragraph, the label shall bear a statement of the quantity of such element in a specified quantity of such food. Except in the case of foods subject to § 125.9, the quantity of food specified as required in this section shall be the quantity customarily or usually consumed during a period of one day, or a quantity reasonably suitable for and practicable of consumption within such period. If the need in human nutrition for such element has not been established, the label shall also bear the statement "The need for ---------- in human nutrition has not been established," the blank to be filled in with the name of such element.

(3) If a food purports to be or is represented for special dietary use by man by reason of its mineral property, and any such use is for treating any disease resulting from a dietary deficiency of any element, the label shall bear a statement of the quantity of such element in a specified quantity of such food. If the represented special dietary use of such food is solely for treating any such disease, such food shall be exempt from the labeling requirements of subparagraphs (1) and (2) of this paragraph when otherwise applicable.

(4) Compliance with the provisions of subparagraphs (2) and (3) of this paragraph shall not be construed as relieving any food which purports to be or is represented for special dietary use by

reason of its mineral property from the application of sections 403 (a) and 201 (n) of the act, as in the case where the need for such element in human nutrition is not substantially supported by the opinion of experts qualified by scientific training and experience to determine such needs.

(b) For the purposes of the regulations in this section, the following are minimum daily requirements:

(1) For calcium (Ca), 750 milligrams for a child or an adult, except a pregnant or lactating woman in which case the minimum daily requirement is 1.5 grams.

(2) For phosphorus (P), 750 milligrams for a child or an adult, except a pregnant or lactating woman in which case the minimum daily requirement is 1.5 grams.

(3) For iron (Fe), 7.5 milligrams for a child less than six years old, 10 milligrams for a child six or more years old or for an adult, except a pregnant or lactating woman in which case the minimum daily requirement is 15 milligrams.

(4) For iodine (I), 0.1 milligram for a child or an adult.

§ 125.5 *Label statements relating to infant food.* If a food which purports to be or is represented for special dietary use is a food for infants, the label shall bear, in case such food is fabricated from two or more ingredients, the common or usual name of each such ingredient including spice, flavoring, and coloring; if such food, or any ingredient thereof in case it is fabricated from two or more ingredients, consists in whole or in part of plant or animal matter and the name of such food or ingredient does not clearly reveal the specific plant or animal which is its source, such name shall be so qualified as to reveal clearly the specific plant or animal which is such source. If such use of the food is by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk, the label shall also bear:

(a) A statement of the percent by weight of moisture, protein, fat, available carbohydrate, crude fiber, calcium (Ca), phosphorus (P), and iron (Fe) contained in such food;

(b) A statement of the number of available calories and of U. S. P. units of vitamin A, vitamin B_1 (thiamine), vitamin C (ascorbic acid), and vitamin D supplied by a specified quantity of such food; and

(c) If less than 30 U. S. P. units of vitamin C (ascorbic acid), less than 50 U. S. P. units of vitamin D, or less than 0.75 milligram of iron (Fe), is supplied by the quantity of such food which, as customarily or usually prepared for consumption, supplies 100 available calories, a statement that additional quantities of such vitamin or iron, as the case may be, should be supplied from other sources.

The provisions of paragraphs (a) and (b) of this section shall not apply to cow's milk and evaporated milk. The provisions of paragraph (c) of this section with respect to vitamin D shall not apply to cow's milk or evaporated milk in which the vitamin D is increased by any means to not less than 135 U. S. P. units to each quart in the case of cow's milk and not less than 7.5 U. S. P. units to each avoirdupois ounce in the case of evaporated milk.

§ 125.6 *Label statements relating to certain food used in control of body weight or in dietary management with respect to disease.* If a food purports to be or is represented for special dietary use by man by reason of its use as a means of regulating the intake of protein, fat, carbohydrate, or calories, for the purpose of controlling body weight, or for the purpose of dietary management with respect to disease, the label shall bear a statement of:

(a) The percent by weight of protein, fat, and available carbohydrates in such food; and

(b) The number of available calories supplied by a specified quantity of such food.

§ 125.7 *Label statements relating to nonnutritive constituents.* If a food purports to be or is represented for special dietary use by man by reason of the presence of any constituent which is not utilized in normal metabolism, the label shall bear a statement of the percent by weight of such constituent, and, in juxtaposition with the name of such constituent, the word "nonnutritive". If such constituent is fibrous plant matter, it shall be considered to be crude fiber and its percent expressed as such. But if such constituent is saccharin or a saccharin salt, the label shall bear, in lieu of such statement and word, the statement "Contains ____ saccharin (or saccharin salt, as the case may be), a nonnutritive, artificial sweetener which should be used only by persons who must restrict their intake of ordinary sweets," the blank to be filled in with the percent by weight of saccharin or saccharin salt in such food. The provisions of this section shall not be construed as authorizing the use of saccharin or its salts in any food other than one for use by persons who must restrict their intake of carbohydrates, or as relieving any food from compliance with any requirement of sections 402 (b) or (d), 403 (g), or other provisions of the act.

§ 125.8 *Label statements relating to hypoallergenic food.* If a food purports to be or is represented for special dietary use by man by reason of the decrease or absence of any allergenic property, the label shall bear:

(a) The common or usual name and the quantity or proportion of each ingredient including spices, flavoring, and coloring, in case the food is fabricated from two or more ingredients;

(b) A qualification of the name of the food, or of the name of each ingredient thereof in case the food is fabricated from two or more ingredients, to reveal clearly the specific plant or animal which is the source of such food or of such ingredient, if such food or such ingredient consists in whole or in part of plant or animal matter and such name does not clearly reveal the specific plant or animal which is such source; and

(c) A statement indicating the nature and effect of any treatment or processing of the food or any ingredient thereof, if the changed allergenic property results from such treatment or processing.

§ 125.9 *Label statements relating to certain foods used as a means of regulating the intake of sodium in dietary management.* If a food purports to be or is represented for special dietary use by man by reason of its use as a means of regulating the intake of sodium or salt (sodium chloride), the label shall bear a statement of the number of milligrams of sodium in 100 grams of the food and a statement of the number of milligrams of sodium in an average serving of the food. The average serving shall be expressed in terms of a convenient unit or units of such food or a convenient unit of measure that can be readily understood and utilized by purchasers of such food. For example, an average serving might be expressed in terms of a number of slices, cookies, wafers, etc., or in terms of cupfuls, tablespoonfuls, teaspoonfuls, etc.

Subchapter C—Drugs

PART 130—DRUGS EXEMPTED FROM PRESCRIPTION-DISPENSING REQUIREMENTS OF SECTION 503 (b) (1) (C) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

CROSS REFERENCE: See § 1.108 of this chapter for general regulations covering exemptions from prescription requirements.

§ 130.1 *Exemption for certain drugs limited by new-drug applications to prescription sale.* (a) The prescription-dispensing requirements of section 503 (b) (1) (C) of the Federal Food, Drug, and Cosmetic Act are not necessary for the protection of the public health with respect to the following drugs subject to new-drug applications:

(1) *N*-acetyl-*p*-aminophenol (*p*-hydroxy-acetanilid) preparations meeting all the following conditions:

(i) The *N*-acetyl-*p*-aminophenol is prepared with or without other drugs in tablet or other dosage form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The *N*-acetyl-*p*-aminophenol and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is effective for it.

(iv) The preparation contains not more than 0.325 gram (5 grains) of *N*-acetyl-*p*-aminophenol per dosage unit.

(v) The preparation is labeled with adequate directions for use in minor conditions as a simple analgesic.

(vi) The dosages of *N*-acetyl-*p*-aminophenol recommended or suggested in the labeling do not exceed: For adults, 0.325 gram (5 grains) per dose or 1.0 gram (15 grains) per 24-hour period; for children 6 to 12 years of age, one-half of the maximum adult dose or dosage.

(vii) The labeling bears, in juxtaposition with the dosage recommendations, a clear warning statement against administration of the drug to children under 6 years of age and against use of the drug for more than 10 days, except as such uses may be directed by a physician.

(2) Sodium gentisate (sodium-2, 5-dihydroxybenzoate) preparations meeting all the following conditions:

(i) The sodium gentisate is prepared, with or without other drugs, in tablet or other dosage form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The sodium gentisate and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is effective for it.

(iv) The preparation contains not more than 0.5 gram (7.7 grains) of anhydrous sodium gentisate per dosage unit.

(v) The preparation is labeled with adequate directions for use in minor conditions as a simple analgesic.

(vi) The dosages of sodium gentisate recommended or suggested in the labeling do not exceed: For adults, 0.5 gram (7.7 grains) per dose or 2.0 grams (31 grains) per 24-hour period; for children 6 to 12 years of age, one-half of the maximum adult dose or dosage.

(vii) The labeling bears, in juxtaposition with the dosage recommendations, a clear warning statement against administration of the drug to children under 6 years of age and against use of the drug for a prolonged period, except as such uses may be directed by a physician.

(3) Isoamylhydrocupreine and zolamine hydrochloride (N, N-dimethyl-N′-2-thiazolyl-N′-ρ-methoxybenzyl-ethylenediamine hydrochloride) preparations meeting all the following conditions:

(i) The isoamylhydrocupreine and zolamine hydrochloride are prepared in dosage form suitable for self-medication as rectal suppositories or as an ointment and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The isoamylhydrocupreine, zolamine hydrochloride, and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is effective for it.

(iv) The preparation contains not more than 0.25 percent of isoamylhydrocupreine and 1.0 percent of zolamine hydrochloride.

(v) If the preparation is in suppository form, it contains not more than 5.0 milligrams of isoamylhydrocupreine and not more than 20.0 milligrams of zolamine hydrochloride per suppository.

(vi) The preparation is labeled with adequate directions for use in the temporary relief of local pain and itching associated with hemorrhoids.

(vii) The directions provide for the use of not more than two suppositories or two applications of ointment in a 24-hour period.

(viii) The labeling bears, in juxtaposition with the dosage recommendations, a clear warning statement against use of the preparation in case of rectal bleeding, as this may indicate serious disease.

(4) Phenyltoloxamine dihydrogen citrate (*N*,*N* dimethyl-(α-phenyl-*O*-toloxy) ethylamine dihydrogen citrate) preparations meeting all the following conditions:

(i) The phenyltoloxamine dihydrogen citrate is prepared, with or without other drugs, in tablet or other dosage form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The phenyltoloxamine dihydrogen citrate and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is effective for it.

(iv) The preparation contains not more than 88 milligrams of phenyltoloxamine dihydrogen citrate (equivalent to 50 milligrams of phenyltoloxamine) per dosage unit.

(v) The preparation is labeled with adequate directions for use in the temporary relief of the symptoms of hay fever and/or the symptoms of other minor conditions in which it is indicated.

(vi) The dosages recommended or suggested in the labeling do not exceed: For adults, 88 milligrams of phenyltoloxamine dihydrogen citrate (equivalent to 50 milligrams of phenyltoloxamine) per dose or 264 milligrams of phenyltoloxamine dihydrogen citrate (equivalent to 150 milligrams of phenyltoloxamine) per 24-hour period; for children 6 to 12 years of age, one-half of the maximum adult dose or dosage.

(vii) The labeling bears, in juxtaposition with the dosage recommendations:

(*a*) Clear warning statements against administration of the drug to children under 6 years of age, except as directed by a physician, and against driving a car or operating machinery while using the drug, since it may cause drowsiness.

(*b*) If the article is offered for temporary relief of the symptoms of colds, a statement that continued administration for such use should not exceed 3 days, except as directed by a physician.

(5) Oxytetracycline and polymyxin B sulfate preparations meeting all the following requirements:

(i) The oxytetracycline and polymyxin B sulfate are prepared in ointment or other dosage form suitable for self-medication by external application to the skin and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The oxytetracycline, polymyxin B sulfate, and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is effective for it.

(iv) The preparation contains per gram an amount of oxytetracycline hydrochloride equivalent to not more than 30 milligrams of oxytetracycline and an amount of polymyxin B sulfate equivalent to not more than 10,000 units of polymyxin B.

(v) The preparation is labeled with adequate directions for use by external application to prevent infection in minor burns, minor wounds, and abrasions.

(vi) The labeling bears, in juxtaposition with the directions for use, clear warning statements against:

(*a*) Use of the preparation in the eye.

(*b*) Use if irritation or infection develops, except as directed by a physician.

(6) Meclizine hydrochloride (1-*p*-chlorobenzhydryl - 4 - *m* - methylbenzylpiperazine dihydrochloride) preparations meeting all the following conditions:

(i) The meclizine hydrochloride is prepared, with or without other drugs, in tablet or other dosage form suitable for oral use in self-medication, and containing no drug limited to prescription sale under the provisions of section 503 (b) (1) of the act.

(ii) The meclizine hydrochloride and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is effective for it.

(iv) The preparation contains not more than 25 milligrams of meclizine hydrochloride per dosage unit.

(v) The preparation is labeled with adequate directions for use in the prevention of motion sickness.

(vi) The dosages recommended or suggested in the labeling do not exceed: For adults, 50 milligrams of meclizine hydrochloride per 24-hour period; for children 6 to 12 years of age, 25 milligrams of meclizine hydrochloride per 24-hour period.

(vii) The labeling bears, in juxtaposition with the dosage recommendations, clear warning statements against:

(*a*) Exceeding the recommended dosage.

(*b*) Administration of the drug to children under 6 years of age, except as directed by a physician.

(*c*) Driving a car or operating machinery while using the drug, since it may cause drowsiness.

(*d*) Keeping the drug within reach of children, if it is in candy form.

(7) Diamthazole dihydrochloride (2-dimethylamino - 6 - (β - diethylamino ethoxy)-benzothiazole dihydrochloride) preparations meeting all the following conditions:

(i) The diamthazole dihydrochloride is prepared with or without other drugs in a dosage form suitable for external application in self-medication as a dusting powder.

(ii) The diamthazole dihydrochloride and all other components of the preparation meet their professed standards of identity, strength, quality, and purity.

(iii) If the preparation is a new drug, an application pursuant to section 505 (b) of the act is effective for it.

(iv) The preparation contains not more than 5 percent by weight of diamthazole dihydrochloride.

(v) The preparation is labeled with adequate directions for use only for adults and children 12 years of age and older in the prevention of athlete's foot.

(vi) The labeling bears, in juxtaposition with the directions for use, clear warning statements against:

(*a*) Application to infants or young children.

(*b*) Use on open cracks or weeping stages of athlete's foot.

(*c*) Contact with mucous membranes.

(*d*) Use in the event of irritation.

PART 141a—PENICILLIN AND PENICILLIN-CONTAINING DRUGS; TESTS AND METHODS OF ASSAY

Sec.
141a.1 Sodium penicillin, calcium penicillin, potassium penicillin; potency.
141a.2 Sodium penicillin, calcium penicillin, potassium penicillin; sterility.
141a.3 Sodium penicillin, calcium penicillin, potassium penicillin; pyrogens.
141a.4 Sodium penicillin, calcium penicillin, potassium penicillin; toxicity.
141a.5 Sodium penicillin, calcium penicillin, potassium penicillin.
141a.6 Sodium penicillin, calcium penicillin, potassium penicillin; penicillin X.
141a.7 Penicillin in oil and wax.
141a.8 Penicillin ointment.
141a.9 Penicillin tablets.
141a.11 Penicillin with aluminum hydroxide gel.
141a.12 Penicillin troches.
141a.13 Penicillin dental cones.
141a.14 Penicillin with vasoconstrictor.
141a.15 Penicillin for surface application.
141a.16 Tablets aluminum penicillin.
141a.17 Penicillin sulfonamide powder.
141a.18 Penicillin vaginal suppositories.
141a.19 Buffered crystalline penicillin.
141a.20 Capsules buffered penicillin with pectin hydrolysate.
141a.22 Penicillin bougies.
141a.23 Crystalline penicillin and epinephrine in oil.
141a.24 Aluminum penicillin.
141a.25 Aluminum penicillin in oil.
141a.26 Procaine penicillin.
141a.27 Procaine penicillin in oil.
141a.28 Crystalline penicillin for inhalation therapy.
141a.29 Procaine penicillin for aqueous injection.
141a.30 Ephedrine penicillin.
141a.31 Ephedrine penicillin tablets.
141a.32 Procaine penicillin and buffered crystalline penicillin for aqueous injection.
141a.33 Buffered penicillin powder.
141a.34 Procaine penicillin and crystalline penicillin in oil.
141a.35 Penicillin - streptomycin ointment, penicillin - dihydrostreptomycin ointment.
141a.36 Penicillin-streptomycin bougies, penicillin - dihydrostreptomycin bougies.
141a.37 Penicillin-bacitracin ointment.
141a.38 Procaine penicillin and streptomycin in oil, procaine penicillin and dihydrostreptomycin in oil.
141a.39 Penicillin and streptomycin, penicillin and dihydrostreptomycin.
141a.40 Penicillin tooth powder.
141a.41 Penicillin-bacitracin troches.
141a.42 Crystalline penicillin and bacitracin.
141a.43 *l*-Ephenamine penicillin G.
141a.44 *l*-Ephenamine penicillin G in oil.
141a.45 *l*-Ephenamine penicillin G for aqueous injection.
141a.46 Procaine penicillin in streptomycin sulfate solution, procaine penicillin in dihydrostreptomycin sulfate solution.
141a.47 Benzathine penicillin G.
141a.48 Benzathine penicillin G oral suspension, benzathine penicillin G for oral suspension.
141a.49 Penicillin - streptomycin-bacitracin ointment, penicillin - dihydrostreptomycin-bacitracin ointment.
141a.50 Penicillin-streptomycin dental cones, penicillin-dihydrostreptomycin dental cones.
141a.51 Diethylaminoethyl ester penicillin G hydriodide.
141a.52 Diethylaminoethyl ester penicillin G hydriodide for aqueous injection.
141a.53 Penicillin-streptomycin implantation pellets, penicillin-dihydrostreptomycin implantation pellets.
141a.54 Benzathine penicillin G for aqueous injection.
141a.55 Benzathine penicillin G and buffered crystalline penicillin for aqueous injection.
141a.56 Chloroprocaine penicillin O.
141a.57 Chloroprocaine penicillin O for aqueous injection.
141a.58 Penicillin-streptomycin vaginal suppositories, penicillin-dihydrostreptomycin vaginal suppositories.
141a.59 Penicillin-streptomycin - bacitracin dental paste, penicillin-dihydrostreptomycin - bacitracin dental paste.
141a.60 Penicillin and dihydrostreptomycin-streptomycin sulfates, procaine penicillin in dihydrostreptomycin - streptomycin sulfates solution.
141a.61 Benzathine procaine-buffered crystalline penicillins for aqueous injection.
141a.62 Benzathine penicillin G and procaine penicillin for aqueous injection.
141a.63 Penicillin - bacitracin - neomycin ointment; penicillin - bacitracin-neomycin in oil.
141a.64 Penicillin-streptomycin tablets, penicillin - dihydrostreptomycin tablets.
141a.65 Procaine penicillin-streptomycin-neomycin in oil; procaine penicillin - dihydrostreptomycin - neomycin in oil; procaine penicillin-streptomycin-neomycin ointment; procaine penicillin-dihydrostreptomycin-neomycin ointment.
141a.66 Capsules procaine penicillin in oil,
141a.67 Procaine penicillin and benzathine penicillin G in streptomycin sulfate solution; procaine penicillin and benzathine penicillin G in dihydrostreptomycin sulfate solution.
141a.68 Benzathine penicillin G and streptomycin, benzathine penicillin G and dihydrostreptomycin.
141a.69 Crystalline penicillin G oral suspension, crystalline penicillin G sodium oral suspension, potassium penicillin G oral suspension.
141a.70 Tablets benzathine penicillin G and crystalline penicillin.
141a.71 Penicillin - streptomycin powder, penicillin - dihydrostreptomycin powder.
141a.72 Dibenzylamine penicillin G (dibenzylamine penicillin G salt).
141a.73 Dibenzylamine penicillin and potassium penicillin powder, buffered.
141a.74 Dibenzylamine penicillin and streptomycin in oil, dibenzylamine penicillin and dihydrostreptomycin in oil.
141a.75 Hydrabamine penicillin G.
141a.76 Hydrabamine penicillin G oral suspension.
141a.77 Capsules crystalline penicillin G.
141a.78 Benzathine penicillin G in oil.
141a.79 Benzathine penicillin G and procaine penicillin G in oil.
141a.80 Benzathine penicillin G-procaine penicillin G-streptomycin in oil; benzathine penicillin G-procaine penicillin G-dihydrostreptomycin in oil.
141a.81 Penicillin V (phenoxymethyl penicillin).
141a.84 Tablets benzathine penicillin G and penicillin V.
141a.85 Capsules penicillin V.
141a.86 Procaine penicillin-streptomycin-polymyxin in oil; procaine penicillin-dihydrostreptomycin - polymyxin in oil.

AUTHORITY: §§ 141a.1 to 141a.86 issued under sec. 701, 52 Stat. 1055; 21 U. S. C. 371. Interpret or apply sec. 507, 59 Stat. 463, as amended; 21 U. S. C. 357.

§ 141a.1 *Sodium penicillin, calcium penicillin, potassium penicillin; potency*—(a) *Cylinders (cups)*. Use stainless steel cylinders with an outside diameter of 8 mm. (±0.1 mm.), an inside diameter of 6 mm. (±0.1 mm.), and a length of 10 mm. (±0.1 mm.).

(b) *Culture media*. Use ingredients that conform to the standards prescribed by the U. S. P. or N. F.

(1) Make nutrient agar for the seed layer and for carrying the test organism as follows:

Peptone	6.0 gm.
Pancreatic digest of casein	4.0 gm.
Yeast extract	3.0 gm.
Beef extract	1.5 gm.
Glucose	1.0 gm.
Agar	15.0 gm.
Distilled water, q. s	1,000.0 ml.

pH 6.5 to 6.6 after sterilization.

(2) Make nutrient agar for the base layer as follows:

Peptone	6.0 gm.
Yeast extract	3.0 gm.
Beef extract	1.5 gm.
Agar	15.0 gm.
Distilled water, q. s	1,000.0 ml.

pH 6.5 to 6.6 after sterilization.

(3) Make nutrient broth, for preparing an inoculum of the test organism, as follows:

Peptone	5.0 gm.
Yeast extract	1.5 gm.
Beef extract	1.5 gm.
Sodium chloride	3.5 gm.
Glucose	1.0 gm.
Dipotassium phosphate	3.68 gm.
Potassium dihydrogen phosphate	1.32 gm.
Distilled water, q. s	1,000.0 ml.

pH 7.0 after sterilization.

In lieu of preparing the media from the individual ingredients specified in paragraph (b) (1), (2), and (3) of this section, they may be made from a dehydrated mixture which, when reconstituted with distilled water, has the same composition as such media. Minor modification of the individual ingredients specified in paragraph (b) (1), (2), and (3) of this section are permissible if the resulting media possess growth-promoting properties at least equal to the media described.

(c) *Working standard*. Keep the working standard (obtained from the Food and Drug Administration) at room temperature in tightly stoppered vials, which in turn are kept in larger stoppered tubes containing a suitable desiccant. Weigh out carefully in an atmosphere of 50 percent relative humidity or less between 4 and 5 milligrams of the working standard and dilute with sterile 1 percent phosphate buffer (pH 6.0) to make a stock solution of any convenient concentration. Keep this solution at a temperature of about 10° C., and use for 2 days only. From this stock solution make appropriate working dilutions.

(d) *Preparation of sample.* Dissolve aseptically, in sterile distilled water, the sample to be tested to make an appropriate stock solution.

(e) *Preparation of plates.* Add 21 ml. of agar to each Petri dish (20 x 100 millimeters). Distribute the agar evenly in the plates and allow it to harden. Use the plates the same day they are prepared. The test organism is M. pyogenes var. aureus (P. C. I. 209-P or American Type Culture Collection 6538P). Maintain the test organism on agar slants and transfer to a fresh agar slant about once a week. Prepare an inoculum for the plates by transferring the culture from the agar slant into broth and incubate at 32° C.–35° C. From 16 to 24 hours thereafter add 2.0 milliliters of this broth culture to each 100 milliliters of agar which has been melted and cooled to 48° C. Mix the culture and agar thoroughly and add 4 milliliters to each of the plates containing the 21 milliliters of the uninoculated agar. Tilt the plates back and forth to spread the inoculated agar evenly over the surface. Porcelain covers glazed on the outside are used. Place four cylinders on the agar surface so that they are at approximately 90° intervals on a 2.8 cm. radius. In so placing the cylinders drop them from a height of ½ inch, using a mechanical guide or device. A suspension of the test organism may be used in place of the broth culture described above in preparing the inoculum for the seeding of plates. Prepare such suspension as follows: Wash the organisms from an agar slant which has been incubated for 24 hours at 32° C.–35° C. and stored for 24 hours at room temperature with 2.0 milliliters of sterile physiological saline onto a large agar surface such as that provided by a Roux bottle containing 300 milliliters of agar. Spread the suspension of organisms over the entire agar surface with the aid of sterile glass beads. Incubate 24 hours at 32° C.–35° C. and store for 24 hours at room temperature. Wash the resulting growth from the agar surface with about 50 milliliters of sterile physiological saline. Standardize this suspension by determining the dilution which will permit 20 percent light transmission through a filter at 6500 Angstrom units in a photoelectric colorimeter. (In the preparation of the suspensions of the test organism on agar slants and Roux bottles, the 24-hour storage periods at room temperature may be omitted if the suspensions will permit 20-percent light transmission through a filter at 6,500 angstrom units in a photoelectric colorimeter). Add 1.5 to 2.0 milliliters of this resulting dilution to each 100 milliliters of agar which has been melted and cooled to 48° C. to prepare the inoculum for the plates. The suspension may be used for one week.

(f) *Assay.* Use four plates for each sample. Fill one cylinder on each plate with a 1.0 unit per milliliter dilution, and one with a 0.25 unit per milliliter dilution, of the working standard. Add the estimated dilutions of 1.0 unit per milliliter and 0.25 unit per milliliter of the sample under test to the remaining two cylinders on each plate. Carefully place the plates in racks and incubate 16 to 18 hours at 32° C.–35° C. After incubation measure the diameter of each circle of inhibition to the nearest 0.5 millimeter using a colony counter with a millimeter scale etched into the supporting glass over the light source. Other measuring devices of equal accuracy may be used.

(g) *Estimation of potency and error.* (1) Use the accompanying chart (Chart 1) and nomograph (Chart 2) for estimating the potency and its error. To use the chart for estimating potency two values, namely, V and W, are required. For each plate calculate two values

$$v=(u_L+u_H)-(s_L+s_H)$$

and

$$w=(u_H+s_H)-(u_L+s_L)$$

where s_H and s_L are the diameters of the zones of inhibition in millimeters of the 1.0 unit and 0.25 unit dilutions of the standard, respectively, and u_H and u_L refer similarly to the corresponding dilutions of the sample under test. The value V is the sum of the v values for all plates and W is the sum of the w values for all plates. To estimate the potency locate the point on the chart corresponding to the values of V and W, and the potency can be read from the radial lines on the chart.

(2) The error of the assay is estimated by using the nomograph which requires five values, namely, the potency, V, W, Rv, and Rw. Rv (the range of the v's) is the highest value of v minus the lowest value of v obtained from the individual plates. Similarly, Rw is the difference between the highest and lowest w values. After obtaining these five values, connect with a straightedge the points corresponding to v and w on the respective scales on the right side of the nomograph. Mark with a pin or sharp-pointed pencil the intersection of the straightedge and the diagonal line of the nomograph. Move the straightedge so that it connects the value of Rw on its scale and the diagonal line at the point of the pin. The value for Q is thus determined by the scale value where the straightedge crosses the line labeled "Q". T is obtained by adding the squares of Q and Rv. On the left side of the chart connect the values of T and W with the straightedge and read the value of the ratio (error of assay-potency) where the straightedge intersects the scale of values for the ratio. This value multiplied by the potency equals the percentage error of the assay. The error of the assay calculated here estimates only how closely one assayist can check himself on any given set of dilutions of unknown and standard. It does not include any errors of weighing or errors due to variations in materials or subdivisions of a lot of penicillin.

The chart for determining potency should not be used for determinations of potency lower than 50 percent or higher than 150 percent of the standard. If the potency lies outside these limits, the assay should be repeated using a higher or lower dilution. The radial lines on the chart beyond these limits permit a rough estimation of potency from as low as 5 percent to as high as 1,000 percent when low values of W are found. If the value of V or W falls outside the limits of the chart, divide both V and W by the same proper number to bring them into the range of the chart and read the potency from the radial lines as before. If 11.4 Rw is greater than W, the slope of the assay does not differ significantly from zero and the assay is invalid. (The figure 11.4 was obtained by use of Student's "t" test for determining the significance of a slope.)

In certain laboratories it has been noted that with the 4 to 1 ratio, involving concentrations of 0.25 unit for the low dose, the zone of inhibition given by this dose may either be too small for accurate reading or have edges which are poorly defined. In order to permit the use of a higher concentration of penicillin for the low dose the third of the attached charts (Chart 3) may be used in assays in which the ratio of doses is 2 to 1, i. e., the high dose (sH) is twice the low dose (sL). As in the preceding chart (Chart 1), if the potency lies outside the limits of 50 percent to 150 percent the assay should be repeated, using a lower or higher dilution. The potencies beyond these limits are to be used for rough estimation purposes only. These extensions can also be used for four (or more) plate assays if both V and W are divided by the same proper number to bring them into the range of the chart. The error of the assay using the ratio of doses 2 to 1 is estimated by using the nomograph (Chart 2) in the same manner as described for the 4 to 1 ratio of doses. However, the resultant error of the assay derived in this manner must be divided by 2 to give the correct error of the assay for the 2 to 1 ratio of doses.

(h) *Assay by alternative methods.* The potency of the sample may also be determined by the iodometric method as described in § 141a.5 (d), or by the standard-curve technique, using a single dose of standard and unknown. In the case of the standard-curve technique, dilute the sample to be tested to 1.0 unit per milliliter (estimated) in 1-percent phosphate buffer pH 6.0. Place six cylinders on the inoculated agar surface so that they are at approximately 60° intervals on a 2.8 cm. radius. Use three plates for each sample. Fill 3 cylinders on each plate with the 1.0 unit/ml. standard and 3 cylinders with the 1.0 unit/ml. (estimated) sample, alternating standard and sample. Incubate the plates for 16 to 18 hours at 32° C.–35° C. and measure the diameter of each circle of inhibition. At the same time prepare a standard curve using concentrations of the standard of 0.6, 0.7, 0.8, 0.9, 1.0, 1.1, 1.2, 1.3, 1.4, and 1.5 units/ml. in sterile 1 percent phos-

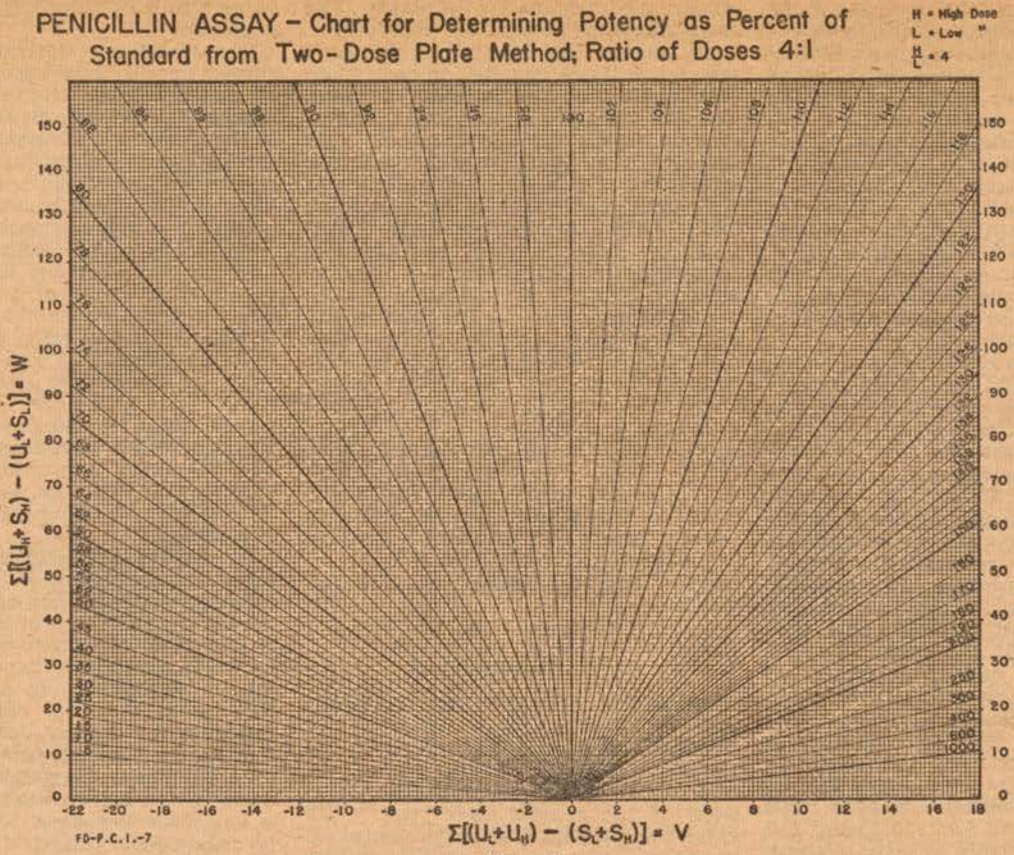

CHART 1.

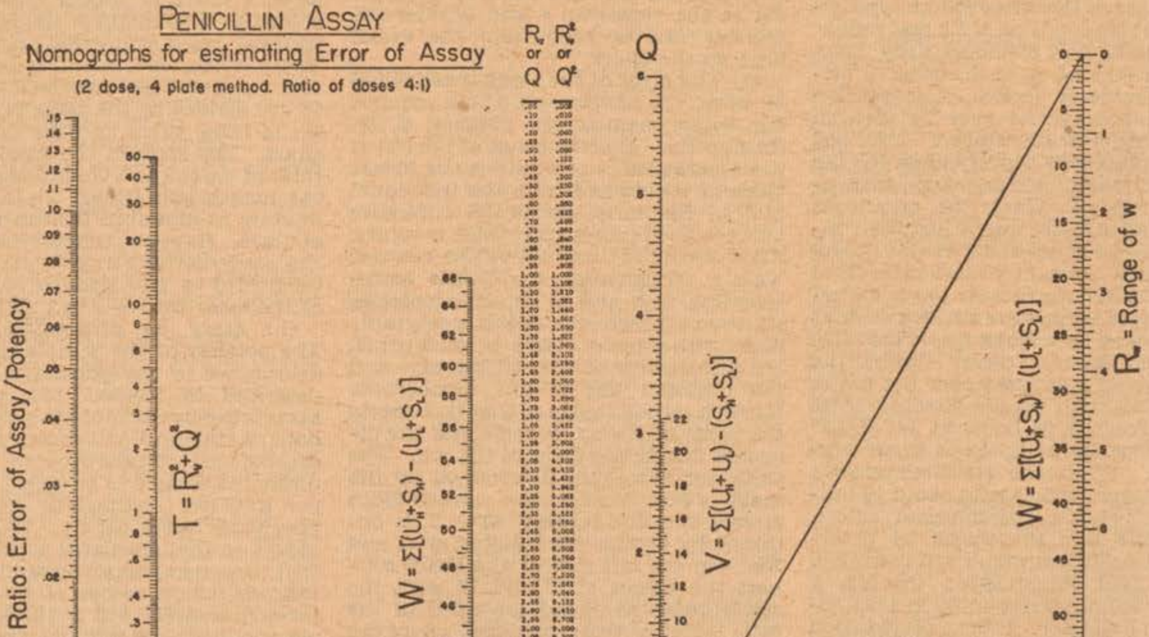

CHART 2.

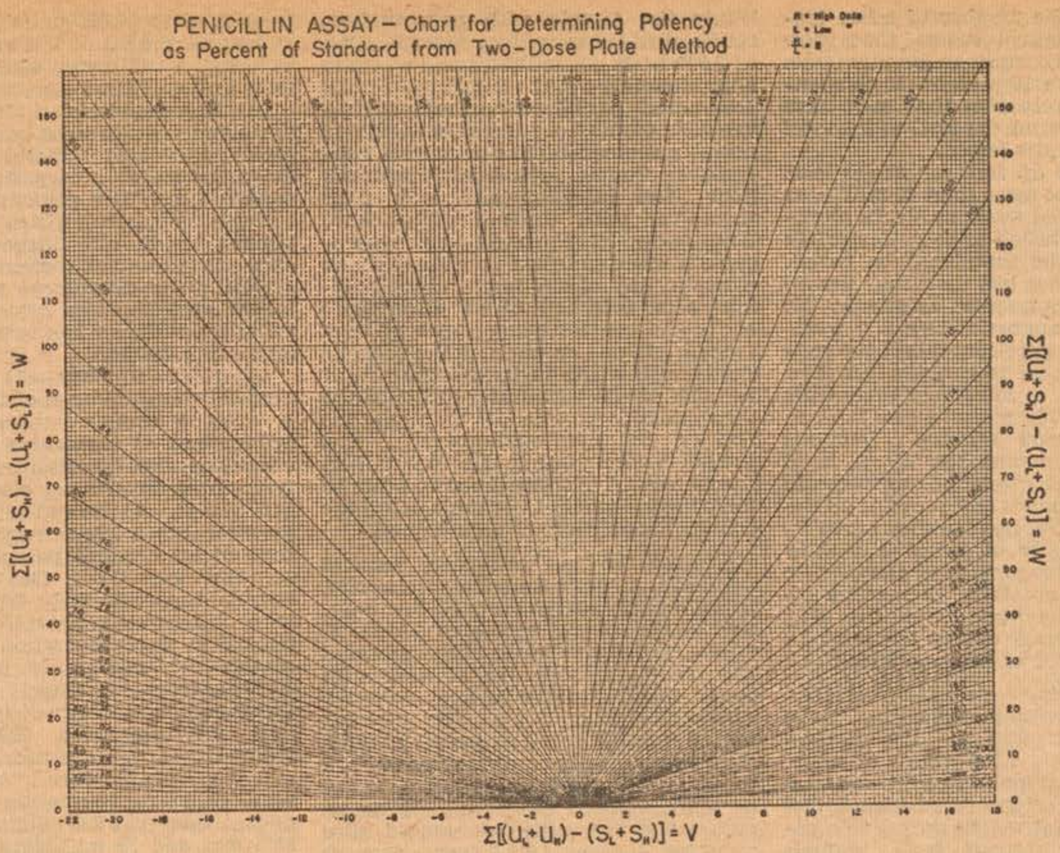

CHART 3.

phate buffer, pH 6.0. Use three plates for the determination of each point on the curve, a total of 27 plates. On each of three plates fill 3 cylinders with the 1.0 unit/ml. standard and the other 3 cylinders with the concentration under test. Thus there will be 81 one-unit determinations and 9 determinations for each of the other points on the curve. After the plates have incubated read the diameters of the circles of inhibition. Average the readings of 1.0 unit/ml. concentration and the readings of the point tested for each set of 3 plates and average also all 81 readings of the 1.0 unit/ml. concentration. The average of the 81 readings of the 1.0 unit/ml. concentration is the correction point for the curve. Correct the average value obtained for each point to the figure it would be if the 1.0 unit/ml. reading for that set of three plates were the same as the correction point. Thus, if in correcting the 0.8 unit concentration, the average of the 81 readings of the 1.0 unit concentration is 20.0 mm., and the average of the 1.0 unit concentration of this set of 3 plates is 19.8 mm., the correction is 0.2 mm. If the average reading of the 0.8 unit concentration of these same 3 plates is 19.0 mm. the corrected value is then 19.2 mm. Plot these corrected values including the average of the 1.0 unit/ml. concentration on 2-cycle semilog paper using the concentration in units per ml. as the ordinate (the logarithmic scale) and the diameter of the zone of inhibition as the abscissa. Draw the standard curve through these points. The 10 points selected to determine the curve are arbitrary and should be so chosen that the limits of the curve will fill the needs of the laboratory. However, the potency of the sample under test should fall in the interval of from 60 percent to 150 percent of the correction point of the standard curve.

To estimate the potency of the sample average the zone readings of the standard and the zone readings of the sample on the three plates used. If the sample gives a larger average zone size than the average of the standard, add the difference between them to the 1.0 unit zone on the standard curve. If the average sample value is lower than the standard value, subtract the difference between them from the 1.0 unit value on the curve. From the curve read the potencies corresponding to these corrected values of zone sizes.

(i) *Potency.* The potency of sodium penicillin, calcium penicillin, and potassium penicillin is satisfactory when assayed by the methods described in this section if the immediate containers are represented to contain:

(1) 200,000 units or less and contain 85 percent or more of the number of units so represented;

(2) More than 200,000 units and contain 90 percent or more of the units so represented.

§ 141a.2 *Sodium penicillin, calcium penicillin, potassium penicillin; sterility*—(a) *Culture medium.* In the test for bacteria, use U. S. P. fluid thioglycolate medium I or a dehydrated mixture which, when reconstituted with distilled water, has the same composition as such medium and has growth-promoting, buffering, and oxygen-tension-controlling properties equal to or better than those of such medium. In the preparation of the medium from either the individual ingredients or any dehydrated mixture avoid contamination with calcium. In the test for molds and yeasts use U. S. P. Sabouraud Liquid Medium (Modified).

(b) *Conduct of test for bacteria.* Add not more than 10 milliliters of sterile distilled water, or sterile physiological salt solution, to each immediate container in the sample to be tested. From each of not less than seven immediate containers transfer aseptically the equivalent of approximately 300 milligrams, or the entire contents if the container is packaged to contain less than 300 milligrams, to individual tubes (38 x 200 millimeter size) each containing 75–100 milliliters of thioglycolate medium and sufficient penicillinase to completely inactivate the penicillin used in the test. (Prior to use, the tubes containing the medium with added penicillinase are incubated at 32° C.—35° C. for not less than 24 hours and examined for sterility.) After adding the penicillin to the tubes let them stand at room temperature for 2 hours, with frequent shaking. To one of such tubes add 1.0 milliliter of a 1:1,000 dilution of an 18–24 hour broth culture of M. pyogenes var. aureus (P. C. I.-209P and American Type Culture Collection 6538P). Incubate all tubes at 32° C.—35° C. for 5 days. The batch meets the requirements of the test for bacteria if on the first or second test the control tube and no other tube shows growth, or if the number of tubes (excluding the control tubes) that show growth in three or more consecutive tests is not more than 10 percent (to compensate for contamination that may have been induced during the test) of the total number of samples tested.

(c) *Conduct of test for molds and yeasts.* Add not more than 10 milliliters of sterile distilled water or sterile physiological salt solution to each immediate container in the sample to be tested. From each of not less than four immediate containers transfer aseptically the equivalent of approximately 300 milligrams, or the entire contents if the container is packaged to contain less than 300 milligrams, to individual tubes each containing 75–100 milliliters of U. S. P. Sabouraud Liquid Medium. Incubate all tubes at approximately 25° C. for 5 days. The batch meets the requirements of the test for molds and yeasts if on the first or second test no tube shows growth, or if the number of tubes that show growth in three or more consecutive tests is not more than 10 percent (to compensate for contamination that may have been induced during the test) of the total number of samples tested.

§ 141a.3 *Sodium penicillin, calcium penicillin, potassium penicillin; pyrogens*—(a) *Test animal.* Use healthy rabbits, weighing 1,500 grams or more, which have been maintained for at least 1 week on a uniform, unrestricted diet and have not lost weight during this period. For subsequent tests, animals utilized for previous tests may be used after a rest period of not less than 2 days. Use a clinical rectal thermometer after it has been tested in a rabbit to determine the time required to reach maximum temperature. (Other recording devices of equal sensitivity are acceptable.) Insert the thermometer or other recording device beyond the internal sphincter and allow it to remain a sufficient time to reach maximum temperature as determined above. Make four rectal temperature readings on each of the animals to be used in the test at 2-hour intervals, 1 to 3 days before such use (this may be omitted for any animal that has been used in such tests during a preceding period of 2 weeks). House the test animals in individual cages and protect them from disturbances likely to cause excitement. Exercise particular care to avoid exciting the animals on the day of taking the control temperatures and on the test day. Maintain the animals in an environment of uniform temperature (±5° F.) at all times.

(b) *Conduct of test.* Heat all syringes and needles to be used in a muffle furnace at 250° C. for not less than 30 minutes to render them pyrogen-free and sterile. Perform the test in a room held at the same temperature as that in which the animals are housed. During the test restrain the animals in individual stocks. On the day of the test do not feed the animals used, until after completion of the test. Take a control temperature reading not more than 15 minutes after the animal is removed from the cage. Use three animals for each test, but do not use those with control temperatures of 38.8° C. or under and 39.9° C. or over. Dilute the sample with pyrogen-free, sterile, distilled water to a concentration of 2,000 units per milliliter and warm to approximately 37° C. Inject 2,000 units (estimated) per kilogram of rabbit intravenously through an ear vein within 15 minutes subsequent to the control temperature reading. Read temperatures 1 hour after injection and each hour thereafter until three readings have been made. The sample is non-pyrogenic if when so tested no animal shows a rise in any of the temperature readings, after injection, of 0.6° C. or more above the control temperature of such animal. If one or more of the animals shows such a rise in temperature, or if the sum of the temperature rises of the three animals exceeds 1.4° C., repeat the test on five additional animals. The sample is nonpyrogenic if not more than one of these five animals shows a rise in temperature of 0.6° C. or more above the control temperature of such animal.

§ 141a.4 *Sodium penicillin, calcium penicillin, potassium penicillin; toxicity.* Inject intravenously each of five mice, within the weight range of 18 to 25 grams, with 0.5 milliliter of a solution of the sample prepared by diluting with sterile distilled water to approximately 4,000 units per milliliter. The injection should be made over a period of not more than 5 seconds. If no animal dies within 48 hours, the sample is nontoxic. If one or more animals die within 48 hours, repeat the test with five unused mice weighing 20 grams (±0.5 gram) each; if all animals survive the repeat test, the sample is nontoxic.

§ 141a.5 *Sodium penicillin, calcium penicillin, potassium penicillin*—(a) *Moisture.* In an atmosphere of about 10 percent relative humidity, transfer about 100 milligrams of the finely powdered sample to a tared weighing bottle or weighing tube equipped with a capillary-tube stopper, the capillary having an inside diameter of 0.20 millimeter–0.25 millimeter. Weigh the bottle or tube and place it in a vacuum oven without removing the stopper and dry at a temperature of 60° C. and a pressure of 5 millimeters of mercury or less for 3 hours. At the end of the drying period, fill the vacuum oven with air dried by passing it through a drying agent such as sulfuric acid or silica gel. Place weighing bottle or tube in a desiccator over a desiccating agent such as phosphorous pentoxide or silica gel, allow to cool to room temperature, and reweigh.

(b) *pH.* Dilute the sample to be tested with carbon-dioxide-free distilled water so that the resulting solution contains 5,000 to 10,000 units per milliliter. Determine the pH of this solution at 25° C. using a pH meter equipped with a glass and a calomel electrode.

(c) *Microscopical test for crystallinity of sodium penicillin and potassium penicillin.* Mount in mineral oil and examine by means of a polarizing microscope. Crystalline penicillin shows resolvable particles which reveal the phenomena of birefringence (interference colors) and extinction positions on revolving the microscope stage. Crystalline penicillin also reveals diagnostic refractive indices when examined by the immersion method.

(d) *Heat stability*—(1) *Crystalline penicillin, crystalline penicillin G.* Store a weighed sample (approximately 30 milligrams) of crystalline penicillin in an unstoppered 50-milliliter Erlenmeyer flask for 4 days in an electric oven at 100° C.±1°. At the end of this period it does not show a loss of more than 10 percent of its original potency when determined as follows: Dilute a weighed sample (approximately 30 milligrams) with a 1-percent phosphate buffer at pH 6.0 to a concentration of approximately 1.2 milligrams per milliliter (2,000 units per milliliter). Add 2.0-milliliter aliquots to each of two 125-milliliter glass-stoppered Erlenmeyer or iodine flasks. To one add 2.0 milliliters of 1 *N* NaOH and allow to stand at room temperature for 15 minutes. At the end of this time add 2.0 milliliters of 1.2 *N* HCl and add 10 milliliters of 0.01 *N* I_2 (prepared from 0.1 *N* I_2 U. S. P.). (Equal volumes of 1 *N* NaOH and 1.2 *N* HCl when mixed give pH 1.0.) After 15 minutes titrate the excess iodine, using 0.01 *N* $Na_2S_2O_3$ (prepared from 0.1 *N* $Na_2S_2O_3$) standardized accurately against potassium iodate. Toward the end of the titration add one drop of starch solution or about 5.0 milliliters of CCl_4. Continue the titration by the addition of 0.01 to 0.02-milliliter portions of 0.01 *N* $Na_2S_2O_3$, shaking vigorously after each addition. The end point is reached when the blue color of the starch-iodine complex is discharged or when the CCl_4 layer becomes colorless. To the second flask add 10 milliliters of 0.01 *N* I_2 and titrate immediately with 0.01 *N* $Na_2S_2O_3$ for the blank determination. Divide the difference in titers by a factor, F, which is the number of milliliters of 0.01 *N* I_2 absorbed by 1.0 milligram of sodium penicillin G working standard, to obtain the milligrams of penicillin sodium salt. Determine the factor F by actual standardization against the sodium penicillin G working standard, using the above method.

$$\text{Units of penicillin G per milligram} = \frac{\text{Difference in titers} \times 1{,}667 \times \text{N of } Na_2S_2O_3}{\text{Milligrams in 2.0 milliliters} \times F \times 0.01}$$

$$\text{Percent loss of potency} = \frac{(\text{Original assay—assay after 4 days at } 100^\circ \text{ C.}) \times 100}{\text{Original assay}}$$

(2) *Crystalline penicillin O.* Proceed as directed in subparagraph (1) of this paragraph, except make the calculations as follows: Divide the difference in titers by a factor, *F*, which is the number of milliliters of 0.01 *N* I_2 absorbed by 1.0 milligram of the penicillin O working standard, to obtain the milligrams of potassium penicillin O. Determine the factor *F* by actual standardization against the penicillin O working standard.

$$\text{Units of penicillin O per milligram} = \frac{\text{Difference in titers} \times 1{,}612 \times \text{N of } Na_2S_2O_3}{\text{Milligrams in 2 milliliters} \times F \times 0.01}$$

Penicillin O does not show a loss of more than 10 percent of its original potency.

(e) *Crystalline penicillin G*—(1) *Reagents.* The reagents described in subdivisions (i), (ii), and (iii) of this subparagraph are freshly prepared every three days and are of such quality that when used in this procedure with a known penicillin G not less than 97 percent of penicillin G is recovered.

(i) *Amyl acetate (iso-amyl acetate) solution.* Saturate the amyl acetate (boiling range 138.5°–141.5° C.) with the *N*-ethyl piperidine salt of penicillin G by adding 2 milligrams of the salt for each 1.0 milliliter of the solvent. Cool this solution to 0°–8° C. and filter it through a sintered-glass filter immediately before use.

(ii) *Acetone solution.* Saturate reagent grade acetone with the *N*-ethyl piperidine salt of penicillin G using 3 mg. of salt for each 1 milliliter of acetone. Cool this solution to 0°–8° C. and filter it through a sintered-glass filter immediately before use.

(iii) *N-ethyl piperidine solution.* *N*-ethyl piperidine (boiling range 129.5°–131.0° C.) should be stored in brown bottles in a refrigerator. Dilute 1.0 milliliter of this reagent with 4.0 milliliters of amyl acetate. Saturate this solution with the *N*-ethyl piperidine salt of penicillin G, using about 3 milligrams of the salt for each 1.0 milliliter of solution. Cool this solution to 0°–8° C. and filter it through a sintered-glass filter immediately before use.

(iv) *Phosphoric acid solution.* Prepare by dissolving 1.0 milliliter of reagent grade phosphoric acid (85 percent) in 4.0 milliliters of water. Cool to 0° to 8° C. and shake before using.

(v) *Silica gel.* Use dry silica gel (mesh size 6–16, Tyler standard). Place about 0.5 gram of the silica gel in a micro filter funnel (approximately 10-millimeter diameter) having a fritted-glass disc of medium porosity.

(2) *Procedure.* Accurately weigh from 60 to 70 milligrams of the sample to be tested in a glass test tube or glass vial of approximately 10 milliliters capacity. Add 2.0 milliliters of water to dissolve the penicillin and cool the solution to 0° to 5° C. Add 2 milliliters of the amyl acetate solution and 0.5 milliliter of the phosphoric acid solution, stopper and shake vigorously for approximately 15 seconds. Centrifuge to obtain a clear separation of the two layers (approximately 20 seconds). After centrifuging, remove as much of the amyl acetate layer as possible (usually about 1.7 milliliters–1.8 milliliters) with a 2-milliliter hypodermic syringe equipped with a suitable needle, and add it to the filter funnel containing the silica gel. Allow the amyl acetate to remain in contact with the silica gel for exactly 20 seconds, then apply suction and collect the filtrate in a small test tube placed in a suction flask surrounded by cracked ice. Pipette a 1.0-milliliter aliquot of the amyl acetate filtrate into a tared flat bottom glass tube (approximately 15 x 50 millimeters) containing 1.0 milliliter of the acetone solution and 0.5 milliliter of the *N*-ethyl piperidine solution. The time elapsing between acidification and the addition of the filtrate to the above reagents should not be more than 3 minutes. Place the glass tube containing this mixture in a large weighing bottle, stopper the bottle and allow to stand for not less than 2 hours in a refrigerator at 0° to 8° C. Remove the liquid from the precipitate by means of a tared micro filter stick and wash with a total of 1 milliliter of the acetone solution adding the latter by means of a hypodermic syringe equipped with a fine needle. Place the filter stick inside the glass tube, dry under vacuum at room temperature for not less than 1 hour, and weigh. (Save all *N*-ethyl piperidine penicillin G residues for saturating reagents.)

$$\text{Percent of sodium penicillin G}=\frac{\text{mg. }N\text{-ethyl piperidine penicillin precipitate}\times 159.3}{\text{Weight of sample mg.}}$$

$$\text{Percent of potassium penicillin G}=\frac{\text{mg. }N\text{-ethyl piperidine penicillin precipitate}\times 166.5}{\text{Weight of sample mg.}}$$

(f) *Penicillin K content.* Determine the content of penicillin K by the following method:

Dilute a weighed sample or the contents of a vial with 0.3 *M* phosphate (Na_2 HPO_4 and KH_2PO_4) buffer pH 6.0 to give a solution containing approximately 1,000 units/ml. In the case of calcium penicillin where a precipitate of calcium phosphate occurs, remove the precipitate by filtration and use the clear filtrate. Place a 15.0-milliliter aliquot of this solution in a 125-milliliter separatory funnel, add 30.0 milliliters of chloroform U. S. P. and shake for 1 minute. (Carry out all operations at room temperature.) Allow the mixture to stand with occasional swirling to settle the droplets of chloroform until the top layer is clear (usually about 10 minutes). Draw off all but about 2 milliliters of the lower chloroform layer through a small pledget of cotton into a glass-stoppered flask. Take a 4.0-milliliter aliquot of the original solution, a 4.0-milliliter aliquot of the buffer solution remaining in the separatory funnel and a 10.0-milliliter aliquot of the chloroform solution and determine the mg./ml. of penicillin in each by the iodometric assay procedure described in paragraph (d) of this section using 4.0 milliliters of the 1 *N* NaOH and 4.0 milliliters of the 1.2 *N* HCl for each of the above aliquots. Make blank determinations on the same size aliquots. Calculate the percent penicillin in the buffer layer and in the chloroform layer as compared to the original solution. The sum of these percentages should be 100%±2%. The percent penicillin K=(96.92+% in chloroform−% in buffer)×1.67. (The factors in the above formula are based on distribution coefficients of penicillin K and G between chloroform and aqueous phosphate buffer at pH 6.0.)

(g) *Penicillin G content of crystalline penicillin O.* Accurately weigh approximately 300 milligrams of the sample to be tested in a 250-milliliter Erlenmeyer flask, dissolve in 1.0 milliliter of 2.5 percent KOH solution, add with swirling 50.0 milliliters of 4.5 percent $KMnO_4$ solution and heat on the steam bath for 2 hours, covering the flask with a watch glass. Cool to room temperature and add 25.0 milliliters of 10 percent oxalic acid solution. When the reaction has ceased, add 15.0 milliliters of 18 *N* H_2SO_4 stepwise with agitation and cooling. Add 30.0 grams of NaCl and agitate until a clear, colorless solution is obtained. Transfer to a separatory funnel and extract with three portions of chloroform, 30 milliliters, 20 milliliters, and 10 milliliters in that order. Filter the extracts through a pledget of cotton previously moistened with chloroform and collect in a second separatory funnel. Add 50.0 milliliters of 0.1 *N* NH_4OH to the combined extracts, shake 5 minutes and allow the phases to separate for 10 minutes. Discard all but a few milliliters of the chloroform layer. Draw off the last few milliliters of chloroform and about 15.0 milliliters of the NH_4OH layer into a glass-stoppered test tube and centrifuge 2 minutes to obtain a clear aqueous layer. Prepare a blank by shaking 50.0 milliliters of 0.1 *N* NH_4OH with 60.0 milliliters of chloroform as described above. Determine the optical density of the blank compared with 0.1 *N* NH_4OH at 220 and 224 mμ. Determine the optical density of the sample at 220 and 224 mμ compared with the blank. Calculate the quantity of benzoic acid in the solution from the equation:

$$x=\frac{RE224-E220}{RB-A}.$$

x=concentration of milligrams per milliliter of benzoic acid in sample.

A=optical density per milligram of benzoic acid U. S. P. per milliliter 0.1 *N* NH_4OH at 220 mμ.

B=optical density per milligram of benzoic acid U. S. P. per milliliter of 0.1 *N* NH_4OH at 224 mμ.

$$R=\frac{\text{optical density of blank at 220 m}\mu}{\text{optical density of blank at 224 m}\mu}.$$

$E220$=optical density of sample at 220 mμ.

$E224$=optical density of sample at 224 mμ.

Calculate the quantity of penicillin G in the sample from the equation:

$$\frac{3.05\times(50)\,(100)}{\text{Weight of sample in milligrams}}=\text{percent penicillin G.}$$

(h) *Penicillin O content.* Determine by means of a suitable infrared spectrophotometer, using the following procedure: Grind the sample to a uniform powder using a mortar and pestle. Weigh by difference, 100–150 milligrams of liquid petrolatum into an agate mortar. Divide the actual weight of the liquid petrolatum by three, and add exactly this amount of the powdered penicillin O to the liquid petrolatum in the mortar. Mix with a small spatula and then mull thoroughly with the pestle until a uniform consistency is obtained. Use two circular rock-salt plates, each 2 inches in diameter as the absorption cell. Place a small drop of the mull in the center of one of the rock-salt plates. Place a brass spacer, 0.0036 inch thick, on the plate. (This spacer is cut in the shape of a circular gasket with a 1-inch center hole and a slit to permit the escape of air when the two plates are pressed together.) Put on the top salt plate gently and slowly squeeze together to spread the mull uniformly. Clamp the two plates firmly together in a metal cell holder. (The cell holder consists of two metal plates, one containing a rectangular center slit ¼ inch wide x ⅝ inch long, the other with a center hole 1 inch in diameter. The two plates are clamped together by means of threaded studs and nuts.) Examine the assembled cell by holding it up to the light. It should appear smooth, free of any air bubbles, and not in contact with the spacer. Adjust the amplification of the spectrophotometer to full-scale deflection for one microvolt, set the slit opening to about 0.300 and run the spectrum from 9.4 to 10.7 microns, using an automatic slit-control mechanism and taking a zero reading (shutter closed) at the beginning and at the end of the run. Draw a base line between two points, one on each side of the analytical band (10.1 microns) and calculate the base-line optical density, using the following formula:

$$D_B = \log 10 \frac{I_B}{I_p}$$

where
D_B = base-line optical density.
I_p = distance from the zero line to the maximum absorption of the band.
I_B = distance from the zero line to the base line, measured at the same wave length as I_p.

Using known mixtures of penicillin G working standard and penicillin O working standard, prepare a standard curve by plotting the base-line optical densities obtained against the percent penicillin O. Obtain the percent penicillin O in the sample under test from this standard curve.

§ 141a.6 *Sodium penicillin, calcium penicillin, potassium penicillin; penicillin X.* Dissolve the contents of a 100,000 unit ampul in about 20 milliliters of ice cold distilled water. Transfer quantitatively to a 100-milliliter volumetric flask, rinsing the ampul with small portions of ice cold water and make to 100 milliliters. Pipette a 50.0-milliliter aliquot into a 125-milliliter separatory funnel, then add 50.0 milliliters of cold chloroform and shake the mixture. Add an amount of approximately 1 *N* H_2SO_4 to bring the pH of the aqueous layer to 2.0. (The amount of 1 *N* H_2SO_4 to be added is calculated by titrating a separate 5.0-milliliter aliquot of the 100-milliliter dilution to pH 2.0 using a suitable pH meter.) Shake the mixture vigorously for one minute. Allow the layers to separate and filter the chloroform through a small pledget of cotton, moistened with chloroform, into a second 125-milliliter separatory funnel. Shake the acid aqueous solution with a second 50.0 milliliters of cold chloroform and, when the layers have separated, withdraw the chloroform through the same filter into the second separatory funnel. Immediately neutralize the acid aqueous solution, containing the penicillin X, with 0.1 *N* NaOH to pH 6.5 to 7.0 using the pH meter and make to 100 milliliters with water. Make appropriate dilutions in 1 percent phosphate buffer at pH 6.0 and assay as directed in § 141a.1 (f) or (h). Shake the combined chloroform extracts, containing any penicillin G, etc., with small successive portions of cold $NaHCO_3$ solution (0.1 percent), until the combined $NaHCO_3$ extracts give a pH of 7.0, and make to 100 milliliters with water. Make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0. Assay these last dilutions as directed in § 141a.1 (f) or (h). The potency of the penicillin X fraction plus potency of the penicillin G, etc., fraction should approximate that of the potency of the original solution. All of the above extractions should be carried out in a cold room.

§ 141a.7 *Penicillin in oil and wax*—(a) *Potency.* Proceed as directed in § 141a.1 except paragraph (i) thereof and, in lieu of the directions in § 141a.1 (d) prepare sample as follows:

Liquefy the sample by warming, thoroughly mix, and withdraw 1.0 milliliter using a sterile syringe equipped with an 18-gauge needle. Transfer to a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake the separatory funnel vigorously to bring about complete mixing of the material with the ether. Shake with a 25-milliliter portion of 1 percent phosphate buffer at pH 6.0. Remove the buffer layer and repeat the extraction with three 25-milliliter quantities of buffer. Combine the extracts and make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0. The sample may also be prepared by transferring aseptically 1.0 milliliter of the penicillin in oil and wax to a blending jar containing 100 milliliters of 1 percent phosphate buffer at pH 6.0. Using a high-speed blender, blend this mixture for 1 minute and then make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0. If the label represents the potency of the penicillin in oil and wax as 200,000 units per milliliter or less, it is satisfactory if it is 85 percent or more of the potency so represented; if represented as more than 200,000 units per milliliter, it is satisfactory if it is 90 percent or more of the potency so represented.

(b) *Sterility.* Transfer aseptically directly to the tubes of the medium the entire contents of single-dose containers or the equivalent of approximately 300 milligrams (activity) from each multiple dose container, and proceed as directed in § 141a.2.

(c) *Moisture*—(1) *Reagents*—(i) *Karl Fischer reagent.* Preserve the reagent in glass-stoppered bottles and use from an all glass automatic burette, protecting the solution from the moisture in the air.

(ii) *Water-methanol solution.* Use methanol containing approximately 1 mg. of water per milliliter. Store the solution in a glass bottle attached to an automatic burette and protect from moisture in the air at all times.

(2) *Standardization of Karl Fischer reagent.* Add a known volume of the Karl Fischer reagent to a suitable titrating vessel which has been previously dried at 105° C. and cooled in a desiccator. Introduce a mechanical stirrer and two platinum electrodes which are connected to a suitable electrometric apparatus for measurement of the endpoint. Start the stirrer and titrate with the water-methanol solution until the endpoint is reached. Calculate the milliliters of Karl Fischer reagent equivalent to each milliliter of water-methanol.

Add an accurately weighed quantity of water (approximately 50 milligrams) to a dry titrating vessel, add an excess of the Karl Fischer reagent and back titrate with the water-methanol solution as above. Calculate the milligrams of water equivalent to each milliliter of the Karl Fischer reagent. Standardize the Karl Fischer reagent in this manner daily.

$$e = \frac{w}{v_1 - v_2 f}$$

where
e = milligrams of water equivalent to 1 ml. Karl Fischer reagent.
w = weight of water in milligrams.
v_1 = volume of Karl Fischer reagent used.
v_2 = volume of methanol used.
f = volume ratio of Karl Fischer reagent to water-methanol solution.

(3) *Procedure.* Transfer 1.0 milliliter of the penicillin in oil and wax to a dry titrating vessel, add 10 milliliters of dry chloroform and an excess of the Karl Fischer reagent and back titrate with the water-methanol solution until the endpoint is reached. Transfer 10 milliliters of the dry chloroform used to a dry titrating vessel, add an excess of Karl Fischer reagent, and titrate with the water-methanol as above. Calculate the milliliters of Karl Fischer reagent equivalent to 10 milliliters of chloroform.

$$\text{Percent moisture} = \frac{(v_1 - v_2 f - b) \times e \times 100}{s \times 1000}$$

where
b = milliliters Karl Fischer reagent equivalent to 10 ml. of chloroform
s = volume of the sample in milliliters.

(d) *Measurement of penicillin particle size.* Vigorously shake the container to obtain an even suspension of the penicillin particles and immediately withdraw therefrom approximately 0.5 milliliter of the drug into a clean, dry, tuberculin syringe using a dry 18-gauge needle. Discard approximately the first 5 drops of the mixture extruded from the needle and then extrude approximately 1 minim of the remaining mixture into a test tube containing 3 to 4 milliliters of light mineral oil. Thoroughly mix the contents of the tube and by means of a bacteriological loop (2 millimeters inside diameter, 22 gauge wire), immediately place one loopful of the suspension on each ruled chamber of a bright line hemocytometer. (It is not necessary to use a cover slip.) Confirm by means of the low power objective of the microscope the even distribution of particles over the ruled areas of both chambers and repeat with another loopful of the suspension if even dispersion is not obtained.

Use a magnification of 430 or 440 diameters and a calibrated ocular micrometer to measure the penicillin particles. For the purpose of measurement and calculation, the predominant type of crystals observed shall be considered to represent the type of crystals present and the thickness and density of all particles shall be considered constant. Center a large penicillin particle in the microscopic field; measure the particle and all other particles in the field and repeat this operation on other fields until at least 200 particles are measured. Particles of less than 5 microns in length are disregarded. The grouping of the particles by length, the midpoint, the ratio of the midpoints, and the square of the ratio of the midpoints for each group are tabulated below:

Group	Length in microns	Mid-point	Ratio of mid-points	$(\text{Ratio})^2$
1	5-14	9.5	1.00	1.00
2	15-29	22.0	2.31	5.34
3	30-49	39.5	4.16	17.31
4	50-69	59.5	6.26	39.19
5	70-99	84.5	8.89	79.03
6	100-149	124.5	13.10	171.61
7	150-199	174.5	18.36	337.09
8	200-249	224.5	23.63	558.38
9	250-300	275.0	28.95	838.10

Calculate the percent particles in each group from the total number measured. Determine the percent relative weight for each group as follows:

Plate type particles. Relative weight = $(\text{ratio})^2 \times \%$ of total particles in group.

$$\%\ \text{relative weight} = \frac{\text{relative weight} \times 100}{\text{total relative weight}}$$

Rod-shaped particles. In the case of rod-shaped particles measure the width as well as the length.

$$\text{Relative weight} = \text{ratio} \times \text{average width} \times \%\ \text{of total particles in group}$$

$$\%\ \text{relative weight} = \frac{\text{relative weight} \times 100}{\text{total relative weight}}$$

When examined by the method described in this section not less than 50 percent of the total relative weight of the penicillin in the drug consists of penicillin having a particle size of not less than 50 microns in length.

§ 141a.8 *Penicillin ointment*—(a) *Potency.* Proceed as directed in § 141a.1, except paragraph (i) of that section, and in lieu of the directions in § 141a.1 (d), prepare the sample by one of the following techniques:

(1) *Extraction.* Place a representative portion of the sample (usually approximate 1 gram, accurately weighed) or the entire contents of a single-dose container in a separatory funnel containing 50 milliliters of peroxide-free ether. If the sample consists of substantially more than 1 gram, use 100 milliliters of peroxide-free ether. Shake the sample and ether until homogeneous. Add 25 milliliters of 1-percent phosphate buffer, pH 6.0, and shake. If the sample consists of substantially more than 1 gram, use 50 milliliters of buffer. Allow the layers to separate. Remove the buffer layer and repeat the extraction with new portions of buffer at least three times and any additional times necessary to ensure complete extraction of the antibiotic. Combine the extractives and make the proper estimated dilutions with buffer.

(2) *Blending.* Place an accurately weighed representative portion of the sample (usually approximately 1 gram), or the entire contents of a single-dose container, in a blending jar containing 1.0 milliliter of a 10-percent aqueous solution of polysorbate 80 and sufficient 1-percent phosphate buffer, pH 6.0, to give a final volume of 200 milliliters. If the sample consists of substantially more than 1 gram, use sufficient buffer to give a final volume of 500 milliliters. Using a high-speed blender, blend the mixture for 2 minutes and then make the proper estimated dilutions with buffer. Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.7 (c), using a weighed sample of approximately 1 gram dissolved in 10 milliliters of a mixture of equal parts of dry chloroform and carbon tetrachloride, but in lieu of calculating the milliliters of Karl Fischer reagent equivalent to 10 milliliters of chloroform, determine the milliliters of reagent equivalent to 10 milliliters of the mixture of chloroform and carbon tetrachloride.

§ 141a.9 *Penicillin tablets*—(a) *Potency*—(1) *Tablets that do not contain benzathine penicillin G or penicillin V.* Proceed as directed in § 141a.1, except paragraph (i) thereof and, in lieu of the directions in § 141a.1 (d), prepare sample as follows: Place 12 tablets in a mortar and add approximately 20 milliliters of 1 percent phosphate buffer at pH 6.0. Disintegrate the tablets by grinding with a pestle. Transfer with the aid of small portions of the buffer solution to a 500 milliliter volumetric flask and make to 500 milliliters by adding sufficient phosphate buffer. Make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0. The sample may also be prepared as follows: Place 12 tablets in a blending jar and add thereto approximately 100 milliliters of a 500 milliliter quantity of 1 percent phosphate buffer at pH 6.0. After blending for 1 minute with a high-speed blender add the remainder of the 500 milliliters of buffer. Blend again for 1 minute and make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0.

(2) *Tablets that contain benzathine penicillin G.* Proceed as directed in § 141a.1, except paragraph (i) of that section, and in lieu of the directions in § 141a.1 (d), prepare the sample as follows: Grind 6 tablets, using a mortar and pestle, and add sufficient formamide or dimethyl formamide (previously adjusted, if necessary, to pH 6 to 7 with a few drops of concentrated H_2SO_4 per liter) to give a concentration of not more than 15,000 units per milliliter. Allow to stand for ½ hour, with frequent agitation, then make the proper estimated dilutions in 1-percent phosphate buffer at pH 6.0.

The average potency of penicillin tablets is satisfactory if they contain not less than 85 percent of the number of units per tablet that they are represented to contain.

(3) *Tablets that contain penicillin V.* Using the penicillin V working standard as the standard of comparison, proceed as directed in subparagraph (1) of this paragraph.

(b) *Moisture.* Use 4 tablets and proceed as directed in § 141a.5 (a), except that if they contain benzathine penicillin G or penicillin V proceed as directed in § 141a.26 (e).

§ 141a.11 *Penicillin with aluminum hydroxide gel*—(a) *Sodium penicillin, calcium penicillin, potassium penicillin.* Proceed as directed in §§ 141a.1, 141a.2, 141a.4, and 141a.5 (a) and (b); if crystalline penicillin, § 141a.5 (c), (d) and (f); and if crystalline penicillin G, § 141a.5 (e).

(b) *Aluminum hydroxide gel.* Thoroughly shake the aluminum hydroxide gel and transfer aseptically 1.0 and 0.1-milliliter portions in triplicate to sterile Petri dishes. Pour into each Petri dish 20 milliliters of nutrient agar, described in § 141a.1 (b) (1), which has been melted and cooled to 48° C. Thoroughly mix the aluminum hydroxide and melted agar. Allow the agar to solidify, invert the Petri dishes, and incubate for 48 hours at 32° C.-35° C. Count the number of colonies appearing on the plates and calculate therefrom the number of viable bacteria per milliliter of the aluminum hydroxide gel.

§ 141a.12 *Penicillin troches*—(a) *Potency.* Proceed as directed in § 141a.1, except paragraph (i) thereof and, in lieu of the directions in § 141a.1 (d), prepare sample as follows:

(1) If the troche does not contain a masticatory substance, proceed as directed in § 141a.9 (a).

(2) If the troche contains paraffin as a masticatory substance, place five troches in a separatory funnel containing 75 ml. of *N*-hexane; shake until the troches are dissolved. Shake with a 25-milliliter portion of 1 percent phosphate buffer at pH 6.0. Remove the buffer layer and repeat the extraction with three 25-milliliter quantities of buffer. Combine the extracts and make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0.

(3) If the troche contains gum as a masticatory substance, cut each of five troches into fine pieces and place in a glass blending jar containing 100 milliliters of a 50 percent acetone-water solution. Using a high-speed blender, blend for 3 to 5 minutes. Add an additional 100 milliliters of a 50 percent acetone-water solution to the blender and blend for an additional 3 to 5 minutes, and then make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0.

The average potency of the troche is satisfactory if it contains not less than 85% of the number of units it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a), or if it contains a masticatory substance proceed as directed in § 141a.7 (c), using 1.0 to 2.0 grams dissolved in 10 milliliters of dry chloroform.

§ 141a.13 *Penicillin dental cones*—(a) *Potency.* Proceed as directed in § 141a.1, except paragraph (i) thereof and, in lieu of the directions in § 141a.1 (d), prepare sample using 5 cones as directed in § 141a.9 (a). The average potency of the cone is satisfactory if it contains not less than 85 percent of the number of units per cone it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a).

§ 141a.14 *Penicillin with vasoconstrictor*—(a) *Penicillin used in the packaged combination*—(1) *Potency.* Unless it is penicillin tablets, proceed as directed in § 141a.1. If it is penicillin tablets, proceed as directed in § 141a.9 (a).

(2) *Toxicity, moisture, pH, crystallinity, heat stability, penicillin G content.* Proceed as directed in §§ 141a.4 and 141a.5.

(b) *Dry mixture of penicillin with vasoconstrictor; potency, moisture.* Proceed as directed in §§ 141a.1 and 141a.5 (a).

§ 141a.15 *Penicillin for surface application*—(a) *Potency.* Proceed as directed in § 141a.9 (a) using the contents of 12 immediate containers.

(b) *Moisture.* Proceed as directed in § 141a.5 (a).

§ 141a.16 *Tablets aluminum penicillin*—(a) *Potency.* Proceed as directed in § 141a.9 (a), using citrate buffer at pH 6.3 for making working dilutions of the working standards and for the sample under test in lieu of phosphate buffer. The citrate buffer is of the following composition:

	Grams
Citric acid	52.9
Sodium hydroxide (pellets)	28.25
Sodium citrate	388.0

Make up to 4000 ml. with distilled water.

(b) *Moisture.* Proceed as directed in § 141a.5 (a).

§ 141a.17 *Penicillin sulfonamide powder*—(a) *Potency.* Proceed as directed in § 141a.9 (a), except prepare the samples as follows: Accurately weigh 0.5 gram from each of the immediate containers and dissolve in 100 milliliters of distilled water. From this solution make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0.

(b) *Moisture.* Proceed as directed in § 141a.5 (a).

(c) *Sterility.* Transfer aseptically directly to the tubes of the medium approximately 0.5 gram from each container tested, and proceed as directed in § 141a.2.

§ 141a.18 *Penicillin vaginal suppositories*—(a) *Potency.* Proceed as directed in § 141a.1 except paragraph (i) thereof and in lieu of the directions in § 141a.1 (d) prepare sample as follows:

Place 5 suppositories in a separatory funnel containing 150 milliliters of peroxide-free ether. Shake the separatory funnel vigorously to bring about complete mixing of the material with the ether. Shake with a 25-milliliter portion of 1 percent phosphate buffer at pH 6.0. Remove the buffer layer and repeat the extraction with three 25-milliliter quantities of buffer. Combine all extracts and make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0. The sample may also be prepared as follows: Place 5 suppositories in a glass blending jar containing 200 milliliters of 1 percent phosphate buffer at pH 6.0. Using a high-speed blender blend for 3 minutes and make the proper estimated dilution in 1 percent phosphate buffer at pH 6.0. The average potency of the suppository is satisfactory if it contains not less than 85 percent of the number of units it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.7 (c) using a weighed suppository dissolved in 10 milliliters of dry chloroform and 2 milliliters of methanol from the titrating burette. (Correct for the amount of moisture in the solvents used.)

§ 141a.19 *Buffered crystalline penicillin.* Proceed as directed in §§ 141a.1, 141a.2, 141a.3, 141a.4, 141a.5 and 141a.6.

§ 141a.20 *Capsules buffered penicillin with pectin hydrolysate*—(a) *Potency.* Proceed as directed in § 141a.1 except paragraph (i) thereof and in lieu of the directions in § 141a.1 (d) prepare samples as follows:

Place the contents of 12 capsules and the empty capsules into a 500-milliliter volumetric flask. Add approximately 200 milliliters of 1 percent phosphate buffer at pH 6.0, shake until the powder has dissolved and the capsules have gelatinized and make to 500 milliliters with the phosphate buffer. Make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0. The average potency of capsules buffered penicillin with pectin hydrolysate is satisfactory if it contains not less than 85 percent of the number of units per capsule it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a) utilizing the contents of 4 capsules.

§ 141a.22 *Penicillin bougies*—(a) *Potency.* Proceed as directed in § 141a.9 (a).

(b) *Moisture.* Proceed as directed in § 141a.7 (c), using 1.0 to 2.0 grams of bougies dissolved in 10 milliliters of dry chloroform if it contains the excipient polyethylene glycol. If it does not contain the excepient polyethylene glycol, proceed as directed in § 141a.5 (a).

§ 141a.23 *Crystalline penicillin and epinephrine in oil*—(a) *Potency.* Proceed as directed in § 141a.7 (a) except the provisions for warming the sample. When examined by the method described in this section the potency of crystalline penicillin and epinephrine in oil is satisfactory if it is 90 percent or more of the potency represented.

(b) *Sterility.* Proceed as directed in § 141a.7 (b).

(c) *Moisture.* Proceed as directed in § 141a.7 (c).

(d) *Epinephrine content*—(1) *Standard curve.* Prepare a stock standard containing 20 milligrams of U. S. P. epinephrine reference standard in 100 milliliters of phosphate buffer at pH 4.0. This buffer is prepared by adjusting 1 percent phosphate buffer pH 6.0 with 1:100 phosphoric acid (ortho 85 percent) to pH 4.0. The stock standard is stored in the refrigerator and may be used as long as it remains colorless. Transfer 1.0, 2.0, 3.0, 4.0, and 5.0 milliliters of the standard to each of five 100-milliliter volumetric flasks using transfer pipettes. Add 4.0, 3.0, 2.0, and 1.0 milliliters of the phosphate buffer pH 4.0 to the first four flasks respectively to give each a total volume of 5 milliliters. Add 1.0 milliliter of 0.1 *N* iodine to each flask, shake for one minute, add 2.0 milliliters of 0.1 *N* sodium thiosulfate and mix the solution. Make each flask to a volume of 100 milliliters with distilled water. Read the percent light transmission of the colored solutions using a 2.0 centimeter cell and a 490 mμ filter in a suitable photoelectric colorimeter. The instrument is balanced so that the 0.2 mg./100 ml. concentration reads 90 percent light transmission. Prepare a standard curve on semilog paper, plotting the percent light transmission on the logarithmic ordinate scale and the concentration on the abscissa.

(2) *Procedure.* Transfer 1.0 milliliter of the sample with the aid of a hypodermic syringe and needle to a screw-cap test tube (about 30 milliliters capacity), add 5.0 milliliters of U. S. P. chloroform and 10.0 milliliters of 1 percent phosphate buffer pH 6.0 from a transfer pipette. Shake thoroughly for one minute, centrifuge to separate the layers and carefully withdraw a 5.0-milliliter aliquot of the buffer layer using a transfer pipette. Transfer the aliquot to a 50-milliliter volumetric flask, add the calculated amount of 1:100 phosphoric acid to bring the pH to 4.0 (amount to be added previously determined by titration of the 1 percent phosphate buffer pH 6.0 with 1:100 phosphoric acid using a pH meter). Add 1.0 milliliter of 0.1 *N* iodine, shake for one minute, add 2.0 milliliters of 0.1 *N* sodium thiosulfate and mix the solution. Make to a volume of 50 milliliters with distilled water. Set the colorimeter at 90 percent light transmission for the 0.2 milligram/100 milliliters standard as directed above and obtain the percent light transmission of the sample. The concentration obtained directly from the standard curve corresponding to the percent light transmission of the sample × 1.05 equals the concentration of the epinephrine per milliliter of the sample. Crystalline penicillin and epinephrine in oil is satisfactory if it contains not less than 0.24 or more than 0.36 milligram epinephrine per milliliter.

§ 141a.24 *Aluminum penicillin*—(a) *Potency.* Proceed as directed in § 141a.1 (a), using citrate buffer as prepared in § 141a.16 (a) in lieu of phosphate buffer.

(b) *Sterility.* Proceed as directed in § 141a.2.

(c) *Pyrogens.* Proceed as directed in § 141a.3, but in lieu of the directions for preparation of sample in paragraph (b) thereof, prepare sample as follows:

Suspend approximately 60 milligrams in 20 milliliters of pyrogen-free sterile physiological salt solution, adding the salt solution in approximately 1-milliliter aliquots and mixing thoroughly after each addition, utilizing a pyrogen-free glass stirring rod. Centrifuge, warm to 37° C., withdraw the clear supernatant solution, and inject 1 milliliter per kilogram of rabbit.

(d) *Toxicity.* Proceed as directed in § 141a.4, utilizing the solution prepared in paragraph (c) of this section.

(e) *Moisture.* Proceed as directed in § 141a.5 (a).

(f) *pH.* Proceed as directed in § 141a.5 (b), using a saturated solution.

(g) *Penicillin K content.* Proceed as directed in § 141a.5 (f).

§ 141a.25 *Aluminum penicillin in oil*—(a) *Potency, sterility.* Proceed as directed in § 141a.7.

(b) *Moisture.* Proceed as directed in § 141a.23 (c).

§ 141a.26 *Procaine penicillin*—(a) *Potency.* Proceed as directed in § 141a.1, or by the iodometric method as described in § 141a.5 (d) (1), except prepare the sample as follows: Dissolve a weighed sample (approximately 50 milligrams) in 2.0 milliliters of redistilled methanol. Further dilute this solution with sufficient 1 percent phosphate buffer pH 6.0 to give a concentration of 2.0 milligrams per milliliter.

(b) *Sterility.* Proceed as directed in § 141a.2.

(c) *Pyrogens.* Proceed as directed in § 141a.3, except use physiological salt solution as the diluent.

(d) *Toxicity.* Proceed as directed in § 141a.4, except use physiological salt solution as the diluent, and inject 0.5 milliliter of a solution containing 2,000 units per milliliter.

(e) *Moisture.* Proceed as directed in § 141a.7 (c), but in lieu of the directions for preparing the sample in subparagraph (3) thereof prepare the sample and calculate as follows: Accurately weigh about 300 milligrams of the sample into a dry titrating vessel, add an excess of the Karl Fischer reagent and back titrate with water-methanol solution until the endpoint is reached.

$$\text{Percent moisture} = \frac{(v_1 - v_2 f) \times e \times 100}{W_s}$$

where W_s = weight of sample in milligrams.

(f) *pH.* Proceed as directed in § 141a.5 (b) using a saturated aqueous solution prepared by adding 300 milligrams per milliliter.

(g) *Microscopical test for crystallinity.* Proceed as directed in § 141a.5 (c).

(h) *Penicillin G content.* Proceed as directed in § 141a.5 (e) using the following formula for calculating the percent of procaine penicillin G:

$$\text{Percent of procaine penicillin G} = \frac{N\text{-ethyl piperidine penicillin precipitate} \times 263.1}{\text{Weight of sample in milligrams}}$$

and in lieu of the first four sentences in § 141a.5 (e) (2) proceed as follows:

Accurately weigh approximately 100 milligrams of the sample to be tested in a glass test tube or glass vial of approximately 10-milliliter capacity. Add 2 milliliters of water and cool to 0° C. to 5° C. Add 2 milliliters of the amyl acetate solution and 0.5 milliliter of the phosphoric acid solution, stopper and shake vigorously for aproximately 15 seconds. Add a second 0.5-milliliter portion of the phosphoric acid solution and shake vigorously again. Centrifuge to obtain a clear separation of the two layers (approximately 20 seconds). If any procaine penicillin remains undissolved, add a third portion of 0.5 milliliter of the phosphoric acid solution and repeat the shaking and centrifugation.

(i) *Penicillin K content.* Weigh from 30–35 milligrams of the sample to be tested in a glass test tube or glass vial of approximately 10-milliliter capacity. Add 2.0 milliliters of chloroform U. S. P. and cool the mixture to 0° C.–5° C. in an ice bath. Add 1.0 milliliter of cold 1–4 phosphoric acid solution, stopper and shake vigorously for 15 seconds. Centrifuge to obtain a clear separation of the layers (approximately 20 seconds). After centrifuging, remove 1.0 milliliter of the chloroform layer with a pipette or syringe equipped with a suitable needle. Immediately place the 1.0 milliliter of chloroform in a 125-milliliter separatory funnel containing 29.0 milliliters of chloroform and 15.0 milliliters of 0.3 *M* phosphate (Na_2HPO_4 and KH_2PO_4) buffer pH 6.0 at room temperature and shake for 1 minute. Allow the mixture to stand with occasional swirling to settle the droplets of chloroform until the top layer is clear (usually about 10 minutes). Draw off all but about 2 milliliters of the lower chloroform layer through a small pledget of cotton into a glass-stoppered flask. Take a 4.0-milliliter aliquot of the buffer solution remaining in the separatory funnel and a 10.0-milliliter aliquot of the chloroform solution and determine the milligrams per milliliter of penicillin in each by the iodometric assay procedure described in § 141a.5 (d) (1) using 4.0 milliliters of the 1 *N* NaOH and 4.0 milliliters of the 1.2 *N* HCl for the two above aliquots. Make blank determinations on the same size aliquots. Calculate the percent penicillin in the buffer layer on the basis that the sum of the penicillin found in the buffer layer and in the chloroform layer is 100 percent. The percent penicillin K=(98.46 − percent found in buffer) ×3.34.

§ 141a.27 *Procaine penicillin in oil*—(a) *Potency.* Proceed as directed in § 141a.1, except paragraph (i) thereof and, in lieu of the directions in § 141a.1 (d), prepare sample as follows: Introduce 1 milliliter of the well-shaken sample by means of a 2-milliliter hypodermic syringe, into a 50-milliliter volumetric flask. Add 3 to 4 cubic centimeters of chloroform, shake the flask well, and make to 50 milliliters with absolute alcohol. Mix thoroughly, withdraw a 1-milliliter aliquot and make the proper estimated dilutions in 1 percent phosphate buffer at pH 6.0. The sample may also be prepared as follows: Introduce 1 milliliter of the well-shaken sample by means of a 2.0-milliliter hypodermic syringe into a blending jar containing 98 milliliters of 1 percent phosphate buffer at pH 6.0 and 1.0 milliliter of polysorbate 80. Using a high-speed blender, blend the mixture for 1 minute and make the proper estimated dilution in 1 percent phosphate buffer at pH 6.0. If the label represents the potency of the procaine penicillin in oil as 100,000 units per milliliter, it is satisfactory if it is 85 percent or more of the potency so represented; if represented as 300,000 units per milliliter, it is satisfactory if it is 90 percent or more of the potency so represented.

(b) *Sterility.* Proceed as directed in § 141a.7 (b).

(c) *Moisture.* Proceed as directed in § 141a.7 (c).

§ 141a.28 *Crystalline penicillin for inhalation therapy*—(a) *Potency.* Proceed as directed in § 141a.1, or by the iodometric method as described in § 141a.5 (d) (1).

(b) *Moisture.* Proceed as directed in § 141a.5 (a), except if it is procaine penicillin proceed as directed in § 141a.26 (e).

§ 141a.29 *Procaine penicillin for aqueous injection*—(a) *Potency.* Proceed as directed in § 141a.1, using a 50 percent acetone-water solution to dissolve the sample, or by the iodometric method as described in § 141a.5 (d) (1), except dissolve the sample in about 5.0 milliliters of redistilled methanol prior to diluting with 1 percent phosphate buffer pH 6.0.

(b) *Sterility.* Use the entire contents of single-dose containers or the equivalent of approximately 300 milligrams (activity) from each multiple-dose container, and proceed as directed in § 141a.2, except if it is the aqueous suspension of the drug and does not contain a preservative, incubate all tubes for 14 days.

(c) *Moisture.* Proceed as directed in § 141a.26 (e).

(d) *Pyrogens.* Proceed as directed in § 141a.3, except use physiological salt solution as the diluent.

(e) *Toxicity.* Proceed as directed in § 141a.4, except use physiological salt solution as the diluent, and inject 0.25 milliliter of a solution containing 4,000 units per milliliter.

(f) *pH*—(1) *Dry mixture of the drug.* Proceed as directed in § 141a.5 (b), using the solution or suspension resulting when the amount of diluent recommended in the labeling is added.

(2) *Aqueous suspension of the drug.* Proceed as directed in § 141a.5 (b), using the undiluted aqueous suspension.

§ 141a.30 *Ephedrine penicillin*—(a) *Potency.* Proceed as directed in § 141a.1, or by the iodometric method as described in § 141a.5 (d) (1), except dilute the sample with sufficient 1 percent phosphate buffer pH 6.0 to give a concentration of 2.0 milligrams per milliliter.

(b) *Sterility.* Proceed as directed in § 141a.2.

(c) *Pyrogens.* Proceed as directed in § 141a.3.

(d) *Toxicity.* Proceed as directed in § 141a.4.

(e) *Moisture.* Proceed as directed in § 141a.5 (a).

(f) *pH.* Proceed as directed in § 141a.5 (b).

(g) *Microscopical test for crystallinity.* Proceed as directed in § 141a.5 (c).

(h) *Penicillin G content.* Proceed as directed in § 141a.5 (e) using an accurately weighed sample of approximately 80 mg. and the following formula for calculating the percent of ephedrine penicillin G:

$$\text{Percent of ephedrine penicillin G} = \frac{\text{Milligrams } N\text{-ethyl piperidine penicillin precipitate} \times 223.2}{\text{Weight of sample in milligrams}}$$

(i) *Penicillin K content.* Proceed as directed in § 141a.5 (f).

§ 141a.31 *Ephedrine penicillin tablets*—(a) *Potency.* Proceed as directed in § 141a.9 (a) or by the iodometric method as described in § 141a.5 (d) (1), using 6 tablets dissolved in sufficient 1 percent phosphate buffer pH 6.0 to give a concentration of 2,000 units per milliliter.

(b) *Moisture.* Proceed as directed in § 141a.5 (a).

§ 141a.32 *Procaine penicillin and buffered crystalline penicillin for aqueous injection*—(a) *Total potency (except in single-dose container), sterility, moisture, pyrogens, toxicity, pH.* Proceed as directed in § 141a.29.

(b) *Buffered crystalline penicillin content*—(1) *Preparation of the solution for assay.* Add the indicated amount of distilled water to the contents of a vial of the sample, and shake well. Withdraw one dose of the suspension with a hypodermic syringe and place in a 10-milliliter volumetric flask. Add 20-percent sodium sulfate solution almost to the mark, centrifuge sufficiently to see the meniscus, make to volume with 20-percent sodium sulfate solution, shake well, and centrifuge to obtain a clear or reasonably clear solution. Dilute a 5.0-milliliter aliquot of this clear solution with 1-percent phosphate buffer, pH 6.0, to give a solution for assay of approximately 2,000 units per milliliter.

(2) *Iodometric assay for total penicillin in the solution for assay.* Determine the quantity of penicillin in the solution for assay by the iodometric assay procedure described in § 141a.5 (d) (1).

(3) *Colorimetric determination of procaine penicillin in the solution for assay.* Transfer an aliquot of the solution for assay to a 50-milliliter volumetric flask. Determine the quantity of procaine penicillin in this solution by the following method:

(i) *Reagents*—(*a*) *Sodium nitrite solution.* Dissolve 0.1 gram of sodium nitrite in 100 milliliters of distilled water. Prepare fresh solution every week and store under refrigeration.

(*b*) *Ammonium sulfamate solution.* Dissolve 0.5 gram of ammonium sulfamate in 100 milliliters of distilled water and store under refrigeration.

(*c*) *N-(1-naphthyl)-ethylenediamine solution.* Dissolve 0.1 gram of *N*-(1-naphthyl)-ethylenediamine dihydrochloride in 100 milliliters of distilled water. Prepare fresh solutions every week and store under refrigeration.

(*d*) *Standard procaine solution.* Prepare a standard solution containing 27.55 milligrams of procaine hydrochloride U. S. P. in a liter of distilled water (each milliliter of the standard solution is equivalent to 60 units of procaine penicillin).

(ii) *Standards.* Transfer, respectively, 1.0, 2.0, 3.0, 4.0, and 5.0 milliliters of the standard solution and 5.0 milliliters of distilled water to each of six 50-milliliter volumetric flasks. Add 4.0, 3.0, 2.0, and 1.0 milliliters of water to the first four flasks, respectively, to give each a volume of 5.0 milliliters.

(iii) *Procedure.* To each flask of the standards and the solution for assay add 5.0 milliliters of 4 *N* HCl, 1.0 milliliter of the sodium nitrite solution, 1.0 milliliter of the ammonium sulfamate, and 1.0 milliliter of the *N*-(1-naphthyl)-ethylenediamine solution. Mix and wait two minutes after each addition. Make each flask to volume of 50 milliliters with distilled water. Determine the absorbency of the colored solutions at 550 mμ in a suitable photo electric colorimeter. The instrument is balanced so that the zero concentration reads zero absorbancy. Plot the standard curve on coordinate graph paper. Obtain the procaine penicillin content of the solution for assay directly from the point on the standard curve corresponding to its absorbancy.

(4) The content of buffered crystalline penicillin in one dose of the product is calculated as follows:

$$A=(B-C)F,$$

where

A = buffered crystalline penicillin content of the product.

B = total number of units of penicillin per milliliter as determined in subparagraph (2) of this paragraph.

C = number of units of procaine penicillin per milliliter as determined in subparagraph (3) of this paragraph.

F = appropriate dilution factor depending on the dilution made in the preparation of the solution for assay.

The content of buffered crystalline penicillin in the batch is satisfactory when determined by the method described in this paragraph if it is not less than 85 percent of that which it is represented to contain.

(c) *Procaine penicillin.* The procaine penicillin content of the batch is the difference between the total potency determined by the method described in paragraph (a) or (d) of this section and the content of the buffered crystalline penicillin determined by the method described in paragraph (b) of this section. The procaine penicillin content of the batch is satisfactory when determined by the method described in this paragraph if it is not less than 85 percent of that which it is represented to contain.

(d) *Total potency of a one-dose container.* Wash out the material remaining in the 10-milliliter volumetric flask referred to in paragraph (b) (1) of this section with 1-percent phosphate buffer, pH 6.0. Dilute to give a concentration of approximately 2,000 units per milliliter, and assay by the iodometric method described in § 141a.5 (d) (1). Obtain the total potency by adding the number of units found in this solution (units per milliliter × volume) to the number of units found (units per milliliter × volume) in the solution assayed in accordance with paragraph (b) (2) of this section.

§ 141a.33 *Buffered penicillin powder.* Proceed as directed in §§ 141a.1 and 141a.5 (a).

§ 141a.34 *Procaine penicillin and crystalline penicillin in oil*—(a) *Total potency.* Proceed as directed in § 147a.27 (a) or by the iodometric assay procedure described in § 141a.5 (d) (1), using in the latter procedure a 0.5-milliliter aliquot of the solution prepared as follows: Introduce 1 milliliter of the well-shaken sample, by means of a hypodermic syringe, into a 50-milliliter volumetric flask. Make to 50 milliliters with chloroform-absolute alcohol (1+1) solvent and shake well.

(b) *Crystalline penicillin.* Proceed as directed in § 141a.32 (b), except prepare the sample as follows: Introduce 1 milliliter of the well-shaken sample, by means of a hypodermic syringe, into a 30-milliliter centrifuge tube equipped with a screw cap. Add 10.0 milliliters of chloroform and 10.0 milliliters of a 20 percent sodium sulfate solution, shake well for about 1 minute and centrifuge to obtain a clear upper layer.

(c) *Procaine penicillin.* The difference between the total penicillin as determined by paragraph (a) of this section and the crystalline penicillin as determined by paragraph (b) of this section represents the amount of procaine penicillin present.

(d) The procaine penicillin and the crystalline penicillin content of the batch are satisfactory when assayed by the methods described in this section if each is not less than 85 percent of that which it is represented to contain.

(e) *Sterility.* Proceed as directed in § 141a.7 (b), except in the case of multiple-dose containers use approximately 400 milligrams (activity) from each container, in lieu of 300 milligrams.

(f) *Moisture.* Proceed as directed in § 141a.7 (c).

§ 141a.35 *Penicillin-streptomycin ointment, penicillin-dihydrostreptomycin ointment*—(a) *Potency*—(1) *Penicillin content.* Proceed as directed in § 141a.8 (a). Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units per gram of ointment that it is represented to contain.

(2) *Streptomycin content.* Proceed as directed in § 141b.101 of this chapter, except paragraph (k) of that section, and in lieu of the directions in § 141b.101 (e) and (j) (3), test a representative portion of the sample (usually approximately 1 gram, accurately weighed) or the entire contents of a single-dose container prepared by one of the following methods:

(i) *To assay by the cup-plate method.* Use either extraction or blending.

(*a*) *Extraction.* Place the sample in a separatory funnel containing approximately 50 milliliters of peroxide-free ether. If the sample consists of substantially more than 1 gram, use 100 milliliters of ether. Shake the sample and ether until homogeneous. Add 20 milliliters of 0.1 *M* potassium phosphate buffer, pH 8.0, and shake. If the sample consists of substantially more than 1 gram, use 50 milliliters of buffer. Allow the layers to separate. Remove the buffer layer and repeat the extraction with new portions of buffer at least three times and any additional times necessary to ensure complete extraction of the antibiotic. Combine the extractives and make up to an appropriate measured volume with buffer. To a suitable aliquot add sufficient penicillinase and let stand for 30 minutes at 37° C. to inactivate the penicillin. After inactivation, make the proper estimated dilution with buffer at pH 8.0.

(b) *Blending.* Place the sample in a blending jar containing 1.0 milliliter of 10-percent aqueous solution of polysorbate 80 and sufficient 0.1 *M* potassium phosphate buffer, pH 8.0, to give a final volume of 500 milliliters. Using a high-speed blender, blend the mixture for 3 minutes. To a suitable aliquot, add sufficient penicillinase and let stand for 30 minutes at 37° C. to inactivate the penicillin. After inactivation, make the proper estimated dilutions with buffer at pH 8.0.

(ii) *To assay by the turbidimetric method.* Place the sample in a separatory funnel containing approximately 50 milliliters of peroxide-free ether. If the sample consists of substantially more than 1 gram, use 100 milliliters of ether. Shake the sample and ether until homogeneous. Add 20 milliliters of distilled water, and shake. If the sample consists of substantially more than 1 gram, use 50 milliliters of water. Allow the layers to separate. Remove the aqueous layer and repeat the extraction with new portions of water at least three times and any additional times necessary to ensure complete extraction of the antibiotic. Combine the extractives, and make to an appropriate measured volume with water. Remove the aliquot and, if the ratio of the content of penicillin to the content of streptomycin is equal to or greater than one unit for each microgram, add sufficient penicillinase and let stand for 30 minutes at 37° C. to inactivate the penicillin. Make the proper estimated dilutions with distilled water. Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(3) *Dihydrostreptomycin content.* Proceed as directed in subparagraph (2) of this paragraph, using the dihydrostreptomycin working standard as a standard of comparison. Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram of ointment that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.8 (b).

§ 141a.36 *Penicillin-streptomycin bougies, penicillin-dihydrostreptomycin bougies*—(a) *Potency*—(1) *Penicillin content.* Proceed as directed in § 141a.9 (a), except the last sentence of that paragraph. Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(2) *Streptomycin content.* Using 12 bougies, proceed as directed in § 141b.101 of this chapter, except paragraph (k) of that section, and if the cup-plate method is used, use potassium phosphate buffer (pH 7.8–8.0) for dissolving the sample in lieu of sterile distilled water as directed in § 141b.101 (e) of this chapter and add sufficient penicillinase to the solution under test to completely inactivate the penicillin present. If the turbidimetric method is used, inactivatiion with penicillinase is not necessary unless the ratio of the content of penicillin to the content of streptomycin is equal to or greater than 1.0 unit for each microgram. Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(3) *Dihydrostreptomycin content.* Proceed as directed in subparagraph (2) of this paragraph, using the dihydrostreptomycin working standard as a standard of comparison. Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.22 (b).

§ 141a.37 *Penicillin bacitracin ointment*—(a) *Potency*—(1) *Penicillin content.* Proceed as directed in §141a.8 (a), except the last sentence of that paragraph. Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units it is represented to contain.

(2) *Bacitracin content.* Proceed as directed in § 141e.402 (a) of this chapter, except that sufficient penicillinase is added to the sample under test to completely inactivate the penicillin present. Its content of bacitracin is satisfactory if it contains not less than 85 percent of the number of units it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.8 (b).

§ 141a.38 *Procaine penicillin and streptomycin in oil, procaine penicillin and dihydrostreptomycin in oil*—(a) *Potency*—(1) *Penicillin content.* Proceed as directed in § 141a.27 (a) except the last sentence thereof. Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units per milliliter that it is represented to contain.

(2) *Streptomycin content.* Using 1 milliliter as the test sample proceed as directed in § 141a.35 (a) (2). Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per milliliter that it is represented to contain.

(3) *Dihydrostreptomycin content.* Using 1 milliliter as the test sample proceed as directed in § 141a.35 (a) (3). Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per milliliter that it is represented to contain.

(b) *Moisture.* Using 1 milliliter as the test sample proceed as directed in § 141a.7 (c).

§ 141a.39 *Penicillin and streptomycin, penicillin and dihydrostreptomycin*—(a) *Potency*—(1) *Sodium or potassium penicillin content.* Proceed as directed in § 141a.32 (b), except prepare the sample as follows: Add the indicated amount of distilled water to the contents of a vial of the sample and shake well. Withdraw one dose of the suspension or solution with a hypodermic syringe and place in a 10-milliliter volumetric flask. Also, with the further exception that in the iodometric assay, one drop of 1.2 *N* HCl is added to the blank immediately before the addition of the 0.01 *N* I_2. The sodium or potassium penicillin content is satisfactory if it is not less than 85 percent of that which it is represented to contain.

(2) *Total penicillin content.* Proceed as directed in § 141a.29 (a) or § 141a.32 (d), except that in the iodometric assay one drop of 1.2 *N* HCl is added to the blank immediately before the addition of the 0.01 *N* I_2.

(3) *Procaine penicillin content.* Proceed as directed in § 141a.32 (c). The procaine penicillin content is satisfactory if it is not less than 85 percent of that which it is represented to contain.

(4) *Streptomycin content.* Proceed as directed in § 141b.101 (j) and (k) of this chapter.

(5) *Dihydrostreptomycin content.* Proceed as directed in § 141b.108 (a) of this chapter.

(b) *Sterility.* Use the entire contents of single-dose containers or the equivalent of approximately 0.5 gram (combined activity) for each multiple-dose container, and proceed as directed in § 141a.2, except that no control tube is used in the test for bacteria.

(c) *Toxicity.* Proceed as directed in § 141a.4, using as a test dose 0.5 milliliter of a solution of the sample containing 1.0 milligram of streptomycin or dihydrostreptomycin per milliliter.

(d) *Pyrogens.* Proceed as directed in § 141a.3, using as a test dose 2 milliliters per kilogram of a solution containing 5 milligrams of streptomycin or dihydrostreptomycin per milliliter.

(e) *Moisture.* Proceed as directed in § 141a.26 (e).

(f) *pH.* Proceed as directed in § 141a.5 (b), using the solution or suspension resulting when the amount of diluent recommended in the labeling is added.

§ 141a.40 *Penicillin tooth powder*—(a) *Potency.* Proceed as directed in § 141a.1.

(b) *Moisture.* Proceed as directed in § 141a.7 (c), but in lieu of the directions for preparing the sample in subparagraph (3) thereof prepare the sample and calculate as follows: Accurately weigh about 1 gm. of the sample into a dry titrating vessel. Add an excess of the Karl Fischer reagent and back titrate immediately with water-methanol solution until the end point is reached. (The entire operation from the addition of the Karl Fischer reagent until the end point is reached should not exceed 1 minute.)

$$\text{Percent moisture} = \frac{(V_1 - V_2 f) \times e \times 100}{W_s},$$

where W_s = weight of sample in milligrams.

§ 141a.41 *Penicillin - bacitracin troches*—(a) *Potency*—(1) *Penicillin content.* Proceed as directed in § 141a.12

(a). Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units per troche that it is represented to contain.

(2) *Bacitracin content.* Proceed as directed in § 141e.403 (a) of this chapter, except that sufficient penicillinase is added to the solution under test to completely inactivate the penicillin present. Its content of bacitracin is satisfactory if it contains not less than 85 percent of the number of units per troche that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a).

§ 141a.42 *Crystalline penicillin and bacitracin*—(a) *Potency*—(1) *Content of penicillin.* Proceed as directed in § 141a.1. Its content of penicillin is satisfactory if it contains not less than 90 percent of the number of units it is represented to contain.

(2) *Content of bacitracin.* Proceed as directed in § 141e.401 (a) of this chapter, except that sufficient penicillinase is added to the sample under test to completely inactivate the penicillin present. Its content of bacitracin is satisfactory if it contains not less than 85 percent and not more than 115 percent of the number of units it is represented to contain.

(b) *Sterility.* Proceed as directed in § 141a.39 (b).

(c) *Toxicity.* Proceed as directed in § 141a.4 except use physiological salt solution as the diluent.

(d) *Pyrogens.* Proceed as directed in § 141a.3 using as a test dose 1.0 milliliter per kilogram of a solution containing 300 units of bacitracin per milliliter. Use physiological salt solution as the diluent.

(e) *Moisture.* Proceed as directed in § 141a.5 (a).

(f) *pH.* Proceed as directed in § 141a.5 (b), using a solution prepared as directed in the labeling for the drug.

§ 141a.43 *l-Ephenamine penicillin G*—(a) *Potency.* Proceed as directed in § 141a.1, except in lieu of paragraph (d) dissolve the sample in sufficient methanol before diluting with sterile distilled water to make an appropriate stock solution.

(b) *Sterility.* Proceed as directed in § 141a.2.

(c) *Pyrogens.* Proceed as directed in § 141a.3, except use physiological salt solution as the diluent and inject 2 milliliters per kilogram of a solution containing 800 units per milliliter.

(d) *Toxicity.* Proceed as directed in § 141a.4, except use physiological salt solution as the diluent and inject, in a 10-second interval, 1.0 milliliter of a solution containing 800 units per milliliter.

(e) *Moisture.* Proceed as directed in § 141a.5 (a).

(f) *pH.* Proceed as directed in § 141a.5 (b), using a saturated aqueous solution prepared by adding 300 milligrams per milliliter.

(g) *Microscopical test for crystallinity.* Proceed as directed in § 141a.5 (c).

(h) *Heat stability.* Proceed as directed in § 141a.5 (d) (1), except prepare the sample as follows: Dissolve the sample in 5 milliliters of redistilled methanol. Further dilute this solution with sufficient 1-percent phosphate buffer pH 6.0 to give a concentration of 2.0 milligrams per milliliter.

(i) *Penicillin G content.* Proceed as directed in § 141a.26 (h) using the following formula for calculating the percent of *l*-ephenamine penicillin G:

$$\text{Percent of } l\text{-ephenamine penicillin G} = \frac{N\text{-ethyl piperidine penicillin precipitate} \times 251}{\text{Weight of sample in milligrams}}$$

(j) *Specific rotation.* Accurately weigh approximately 125 milligrams of the sample in a 25-milliliter glass-stoppered volumetric flask and dissolve in about 15 milliliters of water-acetone (1+1) at 20° C. Dilute to 25 milliliters with water-acetone (1+1) at 20° C. and mix thoroughly. Transfer the solution to a 200-millimeter tube, determine the angular rotation in a suitable polarimeter, using sodium light or a 5,893 Angstrom filter, and calculate the specific rotation. The determination must be completed within ½ hour from the time the solution is prepared.

§ 141a.44 *l-Ephenamine penicillin G in oil*—(a) *Potency.* Proceed as directed in § 141a.27 (a), except the last sentence thereof. If it is represented to contain less than 300,000 units per milliliter, its potency is satisfactory if it contains not less than 85 percent of the number of units so represented. If it is represented to contain 300,000 units per milliliter, its potency is satisfactory if it contains not less than 90 percent of the number of units so represented.

(b) *Sterility.* Proceed as directed in § 141a.7 (b).

(c) *Moisture.* Proceed as directed in § 141a.7 (c).

§ 141a.45 *l-Ephenamine penicillin G for aqueous injection*—(a) *Potency.* Proceed as directed in § 141a.43 (a). Its potency is satisfactory if it contains not less than 90 percent of the number of units it is represented to contain.

(b) *Sterility.* Proceed as directed in § 141a.2, except that prior to sterilization add 0.5 milliliter of polysorbate 80 to each tube of thioglycolate and Sabouraud medium. After sterilization, add sufficient penicillinase to each tube of Sabouraud medium to completely inactivate the penicillin used in the test. During the period of incubation, shake the tubes once daily until solubilization is achieved.

(c) *Moisture.* Proceed as directed in §141a.5 (a).

(d) *Pyrogens.* Proceed as directed in § 141a.3, except use physiological salt solution as the diluent and inject 2 milliliters per kilogram of a solution containing 800 units per milliliter.

(e) *Toxicity.* Proceed as directed in § 141a.4, except use physiological salt solution as the diluent and inject, in a 10-second interval, 1.0 milliliter of a solution containing 800 units per milliliter.

(f) *pH*—(1) *Dry mixture of the drug.* Proceed as directed in § 141a.5 (b), using a saturated aqueous solution prepared by adding 300 milligrams per milliliter.

(2) *Aqueous suspension of the drug.* Proceed as directed in § 141a.5 (b), using the undiluted aqueous suspension.

§ 141a.46 *Procaine penicillin in streptomycin sulfate solution, procaine penicillin in dihydrostreptomycin sulfate solution*—(a) *Potency*—(1) *Procaine penicillin content.* Proceed as directed in § 141a.1, except paragraph (i) thereof. If the iodometric assay is used, 1 drop of the 1.2 *N* HCl is added to the blank immediately before the addition of the 0.01 *N* I_2. Its content of procaine penicillin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(2) *Streptomycin sulfate content.* Proceed as directed in § 141b.101 (j) and (k) of this chapter.

(3) *Dihydrostreptomycin sulfate content.* Proceed as directed in § 141b.103 (a) of this chapter.

(b) *Sterility.* Proceed as directed in § 141a.39 (b).

(c) *Toxicity.* Proceed as directed in § 141a.4, using as a test dose 0.5 milliliter of a solution of the sample containing 1.0 milligram of streptomycin or dihydrostreptomycin per milliliter.

(d) *Pyrogens.* Proceed as directed in § 141a.39 (d).

(e) *pH.* Proceed as directed in § 141a.5 (b), using the undiluted aqueous suspension.

§ 141a.47 *Benzathine penicillin G*—(a) *Potency.* Proceed as directed in § 141a.1, except if the bioassay method is used dissolve the sample to be tested in sufficient dimethyl formamide or formamide prior to diluting with phosphate buffer solution. If the iodometric method is used proceed as directed in § 141a.5 (d), except in preparing the blank solution weigh 30–60 milligrams of the sample and make a suspension of 2 milligrams per milliliter in 1-percent phosphate buffer at pH 6.0. Shake well, pipette 2.0 milliliters into a 125-milliliter glass-stoppered Erlenmeyer flask, add 10 milliliters 0.01 *N* iodine and immediately titrate with 0.01 *N* $Na_2S_2O_3$. In preparing the solution for inactivation dissolve a weighed sample (30–60 milligrams) in sufficient 1 *N* NaOH to give 2.0 milligrams per milliliter. Pipette a 2.0-milliliter aliquot into a 125-milliliter glass-stoppered Erlenmeyer flask, and after 15 minutes add 2.0 milliliters 1.2 *N* HCl and 10 milliliters 0.01 *N* iodine. Allow to stand for 15 minutes and titrate the excess iodine with 0.01 *N* $Na_2S_2O_3$. In calculating the results regard the difference in titers multiplied by 661.8, divided by 4, as the units per milligram.

(b) *Sterility.* Proceed as directed in § 141a.2, except prior to sterilization add 0.5 milliliter of polysorbate 80 to each tube of thioglycolate and Sabouraud's medium, and after sterilization add sufficient penicillinase to each tube of Sabouraud's medium to completely inactivate the penicillin used in the test.

During the period of incubation, shake the tubes at least once daily.

(c) *Toxicity.* Proceed as directed in § 141a.4, except use physiological salt solution as the diluent and inject 0.25 milliliter of a suspension containing 4,000 units per milliliter.

(d) *Pyrogens.* Proceed as directed in § 141a.3, except use physiological salt solution as the diluent and inject 0.5 milliliter per kilogram of rabbit of a suspension containing 4,000 units per milliliter.

(e) *Moisture.* Proceed as directed in § 141a.26 (e).

(f) *pH.* Proceed as directed in § 141a.5 (b), using a saturated aqueous solution prepared by adding 5 milligrams per milliliter.

(g) *Microscopical test for crystallinity.* Proceed as directed in § 141a.5 (c).

(h) *Penicillin G content.* Dissolve 50 milligrams of the sample, accurately weighed, in absolute methyl alcohol and make to a volume of 100 milliliters with absolute methyl alcohol. With a suitable spectrophotometer determine the optical density of the solution in a 1-centimeter cell at 263 mμ compared with absolute methyl alcohol as a blank. Multiply the optical-density figure obtain by the appropriate factor to obtain the optical-density value of a 1-percent solution. The $E_{1\text{ cm.}}^{1\%}$ value of the sample multiplied by 100, divided by 7.0, represents the percent penicillin G in the sample.

§ 141a.48 *Benzathine penicillin G oral suspension, benzathine penicillin G for oral suspension*—(a) *Potency.* Proceed as directed in § 141a.47 (a).

(b) *pH.* Proceed as directed in § 141a.5 (b), using the undiluted aqueous suspension or the suspension prepared as directed in the labeling of the drug.

(c) *Moisture (if it is a dry mixture of the drug).* Proceed as directed in § 141a.26 (e).

§ 141a.49 *Penicillin-streptomycin-bacitracin ointment, penicillin-dihydro-streptomycin-bacitracin ointment*—(a) *Potency*—(1) *Content of penicillin, streptomycin, and dihydrostreptomycin.* Proceed as directed in § 141a.35 (a).

(2) *Bacitracin content.* Proceed as directed in § 141e.402 (a) of this chapter, except that:

(i) Sufficient penicillinase is added to the sample under test to completely inactivate the penicillin present.

(ii) If streptomycin is present add sufficient 0.5 percent semicarbazide solution (pH 6.5–7.0) to inactivate (1 hour at room temperature) the streptomycin.

(iii) If dihydrostreptomycin is present, use as the test organism the Food and Drug Administration dihydrostreptomycin-resistant strain of M. flavus (P. C. I. 16 R. D.), which is grown and maintained in media containing 500 micrograms of dihydrostreptomycin per milliliter of media, or calculate from the quantity of dihydrostreptomycin found, using the method prescribed by subparagraph (1) of this paragraph, the quantity of dihydrostreptomycin that would be present when the sample is diluted to contain 1 unit of bacitracin (labeled potency) per milliliter. Prepare the bacitracin standard curve by adding the calculated quantity of dihydrostreptomycin to each concentration of bacitracin used for the curve. Use this standard curve to calculate the bacitracin content of the sample.

(b) *Moisture.* Proceed as directed in § 141a.8 (b).

§ 141a.50 *Penicillin-streptomycin dental cones, penicillin-dihydrostreptomycin dental cones*—(a) *Potency*—(1) *Penicillin content.* Proceed as directed in § 141a.9 (a). Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(2) *Steptomycin content.* Proceed as directed in § 141a.36 (a) (2). Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(3) *Dihydrostreptomycin content.* Proceed as directed in § 141a.36 (a) (3). Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a).

§ 141a.51 *Diethylaminoethyl ester penicillin G hydriodide*—(a) *Potency.* Proceed as directed in § 141a.1, except prepare the sample as follows: Dissolve in 0.1 *M* potassium phosphate buffer (pH 7.8–8.0) to make a stock solution of 100 units per milliliter (estimated). Allow to stand at room temperature for not less than 1.5 hours and not more than 2 hours and then dilute an aliquot with 1-percent phosphate buffer (pH 6.0) to 1.0 unit (estimated), or proceed by the iodometric method described in § 141a.5 (d) (1), except prepare the sample as follows: Dissolve a weighed sample (approximately 50 milligrams) in 2.0 milliliters of redistilled methanol. Further dilute this solution with 1-percent phosphate buffer (pH 6.0) to give a concentration of 2,000 units per milliliter.

(b) *Sterility.* Proceed as directed in § 141a.2, except in the test for bacteria add for each 100 milliliters of media used 0.5 milliliter of polysorbate 80 and a sufficient quantity of 2 *N* NaOH to produce a solution having a pH of approximately 7.9 after sterilization.

(c) *Pyrogens.* Proceed as directed in § 141a.3, except use physiological salt solution as the diluent.

(d) *Toxicity.* Proceed as directed in § 141a.4, except use physiological salt solution as the diluent, and inject 0.5 milliliter of a solution containing 2,000 units per milliliter.

(e) *Moisture.* Proceed as directed in § 141a.5 (a).

(f) *pH.* Proceed as directed in § 141a.5 (b), using a saturated aqueous solution prepared by adding 300 milligrams per milliliter.

(g) *Microscopical test for crystallinity.* Proceed as directed in § 141a.5 (c).

(h) *Penicillin G content.* Accurately weigh approximately 50 milligrams of the sample and dissolve in 25-milliliter potassium phosphate buffer, pH 7.9 (one part of 0.1 *M* KH_2PO_4, and 11.66 parts of 0.1 *M* K_2HPO_4). Allow to stand at room temperature for not less than 1.5 hours and not more than 2 hours. Transfer a 5.0-milliliter aliquot to a 25-milliliter glass-stoppered test tube. Place the tube in an ice bath and add 10.0 milliliters of chloroform (previously washed with water). After cooling, adjust the pH of the aqueous phase to 2.0 by adding 0.5 milliliter of 1–4 H_3PO_4. Shake the tube thoroughly for 2 minutes, centrifuge, and withdraw the lower chloroform layer with the aid of a 10-milliliter hypodermic syringe and a 3-inch needle. Superficially dry the chloroform by filtering through a pledget of cotton, using a U-shaped funnel to reduce evaporation during filtration. Determine the optical density of the filtered chloroform solution in a 1-centimeter cell at 265 mμ and 280 mμ, using a suitable spectrophotometer. Treat the working standard of sodium penicillin G in the same manner, using an accurately weighted sample of approximately 30 milligrams.

$$\text{Percent penicillin G}=\frac{(O.\,D.\ x \text{ at } 265\text{m}_\mu - O.\,D.\ x \text{ at } 280\text{m}_\mu)\ (\text{wt. } s)\ (100)}{(O.\,D.\ s \text{ at } 265\text{m}_\mu - O.\,D.\ s \text{ at } 280\text{m}_\mu)\ (\text{wt. } x)\ (0.635)}$$

where $O.\,D.$ = optical density,
x = diethylaminoethyl ester penicillin G hydriodide,
s = sodium penicillin G working standard.

§ 141a.52 *Diethylaminoethyl ester penicillin G hydriodide for aqueous injection*—(a) *Potency.* If the bioassay method is used, proceed as directed under § 141a.51 (a). If the iodometric method is used, proceed as directed under § 141a.5 (d) (1). Its potency is satisfactory if it contains not less than 90 percent of the number of units it is represented to contain.

(b) *Sterility.* Use the entire contents of single-dose containers or the equivalent of approximately 300 milligrams (activity) from each multiple-dose container, and proceed as directed in § 141a.51.

(c) *Moisture.* Proceed as directed in § 141a.5 (a).

(d) *Pyrogens.* Proceed as directed in § 141a.3, except use physiological salt solution as the diluent.

(e) *Toxicity.* Proceed as directed in § 141a.4, except use physiological salt solution as the diluent, and inject 0.5 milliliter of a solution containing 2,000 units per milliliter.

(f) *pH.* Proceed as directed in § 141a.5 (b), using a saturated aqueous solution prepared by adding 300 milligrams per milliliter.

§ 141a.53 *Penicillin-streptomycin implantation pellets, penicillin-dihydrostreptomycin implantation pellets*—(a) *Potency*—(1) *Penicillin content.* Proceed as directed in § 141a.9 (a). Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(2) *Streptomycin content.* Proceed as directed in § 141a.36 (a) (2). Its content of streptomycin is satisfactory if it con-

tains not less than 85 percent of the number of milligrams that it is represented to contain.

(3) *Dihydrostreptomycin content.* Proceed as directed in § 141a.36 (a) (3). Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a).

§ 141a.54 *Benzathine penicillin G for aqueous injection*—(a) *Potency.* Proceed as directed in § 141a.47 (a). Its potency is satisfactory if it contains not less than 90 percent of the number of units that it is represented to contain.

(b) *Sterility.* Proceed as directed in § 141a.47 (b).

(c) *Moisture (dry mixture of the drug).* Proceed as directed in § 141a.26 (e).

(d) *Pyrogens.* Proceed as directed in § 141a.47 (d).

(e) *Toxicity.* Proceed as directed in § 141a.47 (c).

(f) *pH*—(1) *Dry mixture of the drug.* Proceed as directed in § 141a.47 (f).

(2) *Aqueous suspension of the drug.* Proceed as directed in § 141a.47 (f), using the undiluted aqueous suspension.

§ 141a.55 *Benzathine penicillin G and buffered crystalline penicillin for aqueous injection*—(a) *Total potency (except in single-dose containers).* Proceed as directed in § 141a.1, except if the bioassay method is used prepare the sample by diluting 1.0 milliliter of the drug suspension with sufficient dimethyl formamide or formamide to dissolve the benzathine penicillin G. Make to 100 milliliters with buffer. Shake well and dilute to 1.0 unit per milliliter. If the iodometric method is used, proceed as directed in § 141a.47, except in preparing the blank solution dilute 1.0 milliliter of the drug suspension to 250 milliliters with 1-percent phosphate buffer at pH 6.0. In preparing the solution for inactivation dissolve 1.0 milliliter of the drug suspension in approximately 20 milliliters of 0.5 *N* NaOH. Allow to stand for 15 minutes. Dilute to 250 milliliters with distilled water. Pipette a 2.0-milliliter aliquot into a 125-milliliter glass-stoppered Erlenmeyer flask and add 2.0 milliliters 1.2 *N* HCl and 10 milliliters 0.01 *N* iodine.

(b) *Buffered crystalline penicillin content.* Place 1.0 milliliter of the drug suspension in a 10-milliliter volumetric flask and add 20 percent sodium sulfate to make 10 milliliters. Shake well and centrifuge to obtain a clear, or reasonably clear, solution. Dilute a 5.0-milliliter aliquot to 50 milliliters with buffer and proceed as directed in § 141a.1 to determine the number of units per milliliter of this solution, and from this value calculate the number of units per milliliter of the drug. The content of buffered crystalline penicillin is satisfactory if it is not less than 85 percent of that which it is represented to contain.

(c) *Benzathine penicillin G content.* The benzathine penicillin G content of the batch is the difference between the total potency as described in paragraph (a) or (d) of this section and the content of buffered crystalline penicillin determined by the method prescribed in paragraph (b) of this section. The content of benzathine penicillin G is satisfactory if it is not less than 85 percent of that which it is represented to contain.

(d) *Total potency of a single-dose container.* Add sufficient distilled water to the material remaining in the 10-milliliter volumetric flask referred to in paragraph (b) of this section to bring the volume back to 10 milliliters and determine the number of units per milliliter of this suspension. If the iodometric method is used, 2.0-milliliter aliquots are placed in 50-milliliter volumetric flasks (one blank and one to be inactivated). Obtain the total potency by adding the number of units found in the 10-milliliter volumetric flask to one-half the content of buffered crystalline penicillin found in paragraph (b) of this section.

(e) *Sterility.* Proceed as directed in § 141a.47 (b).

(f) *Moisture.* Proceed as directed in § 141a.26 (e).

(g) *Pyrogens.* Proceed as directed in § 141a.47 (d).

(h) *Toxicity.* Proceed as directed in § 141a.47 (c).

(i) *pH.* Proceed as directed in § 141a.47 (f).

§ 141a.56 *Chloroprocaine penicillin O*—(a) *Potency, sterility, pyrogens, toxicity, moisture, pH, and crystallinity.* Proceed as directed in § 141a.26.

(b) *Chloroprocaine penicillin O content.* Accurately weigh approximately 168 milligrams of the sample in a 25-milliliter glass-stoppered test tube and add 5.0 milliliters of chloroform (previously washed with water) and 15 milliliters of distilled water. Place the tube in an ice bath for 5 minutes and then add 1.5 milliliters of 1–4 H_3PO_4. Shake the tube vigorously for 2 minutes, centrifuge for 1 minute to separate the layers, and withdraw the lower chloroform layer with the aid of a 10-milliliter hypodermic syringe equipped with a 3-inch needle. Superficially dry the chloroform by filtering through a pledget of cotton, using a U-shaped funnel to reduce evaporation during filtration. Collect the filtrate in a 5-milliliter glass-stoppered bottle and use within an hour. Place this chloroform solution in the absorption cell (consisting of two rock-salt plates with a 1.0-millimeter polyethylene spacer between them, clamped firmly in the cell holder). Adjust the amplification of the infrared spectrometer to full-scale deflection for 1 microvolt, set the slit opening at 0.300 millimeter and record the spectrum from 10.7 to 9.4 microns, taking a zero reading (shutter closed) at the beginning and at the end of the run. Draw a base line from the transmission peak at 10.3 microns parallel to the zero line. Calculate the base line optical density from the following formula:

$$D_B=\log_{10}\frac{I_B}{I_P}$$

where

D_B=base line density.

I_B=distance from the zero line to the base line measured at the transmission peak at 10.3 microns.

I_P=distance from the zero line to the maximum absorption of the band at 10.1 microns.

The extinction coefficient of the sample in the particular cell being used is calculated as follows:

$$E=\frac{D_e\times 5}{\text{Weight of sample in grams}}$$

where E=extinction coefficient.

Using an accurately weighed sample of about 100 milligrams of the potassium penicillin O working standard in the above procedure, determine its extinction coefficient in the particular cell being used.

Obtain the percent chloroprocaine penicillin O in the sample under test by the following calculation:

$$\frac{E\text{ sample}}{E\text{ standard}}\times 68=\text{percent chloroprocaine penicillin O.}$$

(c) *Chloroprocaine penicillin G content.* Proceed as directed in § 141a.5 (g), except prepare the sample as follows: Accurately weigh approximately 500 milligrams of the sample in a 25-milliliter glass-stoppered test tube. Add 6 milliliters of distilled water and 6.0 milliliters of amyl acetate. Place the tube in an ice bath for 5 minutes and then add 4 milliliters of 1–4 H_3PO_4, shake vigorously for 2 minutes, centrifuge for 1 minute to separate the layers, and withdraw 5.0 milliliters of the amyl acetate layer. Place the amyl acetate in a 250-milliliter Erlenmeyer flask and evaporate to dryness by directing a stream of air into the flask. Dissolve the residue in 2.0 milliliters of 2.5 percent KOH.

Calculate the percent of penicillin G in the sample from the equation:

$$\frac{(5.10)\,(x)\,(50)\,(100)}{(\text{Wt. sample milligrams})\ (0.833)}=\text{percent penicillin G}$$

§ 141a.57 *Chloroprocaine penicillin O for aqueous injection.* For the determination of potency, sterility, moisture, pyrogens, toxicity, and pH, proceed as directed in § 141a.29.

§ 141a.58 *Penicillin-streptomycin vaginal suppositories, penicillin-dihydrostreptomycin vaginal suppositories*—(a) *Potency*—(1) *Penicillin content.* Proceed as directed in § 141a.18 (a). Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(2) *Streptomycin content.* Using 5 suppositories, proceed as directed in § 141a.35 (a) (2), except that 150 milliliters of peroxide-free ether is used in the extraction. Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(3) *Dihydrostreptomycin content.* Proceed as directed in subparagraph (2) of this paragraph, using the dihydrostreptomycin working standard as a standard of comparison. Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.18 (b).

§ 141a.59 *Penicillin-streptomycin-bacitracin dental paste, penicillin-dihydrostreptomycin-bacitracin dental* *paste*—(a) *Potency.* Proceed as directed in § 141a.49 (a).

(b) *Moisture.* Proceed as directed in § 141a.8 (b).

(c) *Sterility.* Proceed as directed in §141a.7 (b).

§ 141a.60 *Penicillin and dihydrostreptomycin-streptomycin sulfates, procaine penicillin in dihydrostreptomycin-streptomycin sulfates solution*—(a) *Potency*—(1) *Penicillin content.* If it contains:

(i) *Crystalline penicillin and dihydrostreptomycin-streptomycin sulfates.* Proceed as directed in § 141a.1, except that if the iodometric assay is used 1 drop of 1.2 *N* HCl is added to the blank immediately before the addition of the 0.01 *N* I_2; or

(ii) *Procaine penicillin and dihydrostreptomycin-streptomycin sulfates.* Proceed as directed in § 141a.29 (a), except that in the iodometric assay 1 drop of 1.2 *N* HCl is added to the blank immediately before the addition of the 0.01 *N* I_2; or

(iii) *Benzathine penicillin G and dihydrostreptomycin - streptomycin sulfates.* Proceed as directed in § 141a.47 (a), except that in the iodometric assay 1 drop of 1.2 *N* HCl is added to the blank immediately before the addition of the 0.01 *N* I_2; or

(iv) *Crystalline penicillin-procaine penicillin and dihydrostreptomycin-streptomycin sulfates.* Proceed as directed in § 141a.32 (a), (b), and (c), except that in the iodometric assay 1 drop of 1.2 *N* HCl is added to each blank immediately before the addition of the 0.01 *N* I_2; or

(v) *Crystalline penicillin-benzathine penicillin G and dihydrostreptomycin-streptomycin sulfates.* Proceed as directed in § 141a.55 (a), (b), (c), and (d), except that in the iodometric assay 1 drop of 1.2 *N* HCl is added to each blank immediately before the addition of the 0.01 *N* I_2; or

(vi) *Crystalline penicillin-procaine penicillin-benzathine penicillin G and dihydrostreptomycin-streptomycin sulfates.* Proceed as directed in § 141a.61 (a) (1), (2), (3), and (4), except that in the iodometric assay 1 drop of 1.2 *N* HCl is added to each blank immediately before the addition of the 0.01 *N* I_2; or

(vii) *Procaine penicillin-benzathine penicillin G and dihydrostreptomycin-streptomycin sulfates.* Proceed as directed in § 141a.67 (a) (1) and (2).

The total potency and the number of units of each salt of penicillin are satisfactory if the immediate containers contain not less than 85 percent of the number of units that they are represented to contain.

(2) *Combined potency of dihydrostreptomycin and streptomycin; content of streptomycin.* Proceed as directed in § 141b.118 (a) and (b) of this chapter. Its combined potency of streptomycin and dihydrostreptomycin is satisfactory if it is not less than 90 percent of the number of milligrams that it is represented to contain. Its content of streptomycin is satisfactory if it contains not less than 45 percent and not more than 55 percent of the combined potency of streptomycin and dihydrostreptomycin.

(b) *Sterility.* Proceed as directed in § 141a.39 (b), except if it contains benzathine penicillin G proceed as directed in § 141a.47 (b).

(c) *Toxicity.* Proceed as directed in § 141a.39 (c), except if it contains benzathine penicillin G, proceed as directed in § 141a.47 (c), using a test suspension containing a total penicillin activity of 4,000 units per milliliter.

(d) *Pyrogens.* Proceed as directed in § 141a.39 (d), except if it contains benzathine penicillin G proceed as directed in § 141a.47 (c), using a test suspension containing a total penicillin activity of 4,000 units per milliliter.

(e) *Moisture.* Proceed as directed in § 141a.5 (a), except if it contains procaine penicillin or benzathine penicillin G proceed as directed in § 141a.26 (e).

(f) *pH.* Proceed as directed in § 141a.29 (f).

§ 141a.61 *Benzathine-procaine-buffered crystalline penicillins for aqueous injection*—(a) *Potency*—(1) *Total potency.* Proceed as directed in § 141a.1, except if the bioassay method is used prepare the sample by diluting one dose of the drug suspension with sufficient dimethyl formamide or formamide to dissolve the benzathine penicillin G. Make to 100 milliliters with 1-percent phosphate buffer, pH 6.0. Shake well, and dilute to 1.0 unit per milliliter with buffer. If the iodometric method of assay is used, add the indicated amount of distilled water to the contents of a vial of the sample, shake well, and proceed as follows (except for single-dose containers):

(i) Using a standardized hypodermic syringe, withdraw one dose and dilute with 1-percent phosphate buffer, pH 6.0, to give a concentration of approximately 2,000 units per milliliter. Use 2.0 milliliters of this suspension as the blank in the iodometric assay procedure described in § 141a.5 (d) (1).

(ii) Using a standardized hypodermic syringe, withdraw another dose, place in a flask, and add 20 milliliters of 0.5 *N* NaOH for each 300,000 units of benzathine penicillin, mix well, being sure that all penicillin is in solution, and allow to stand for 15 minutes. Add 1 milliliter of 1.2 *N* HCl for each 2 milliliters of 0.5 *N* NaOH, mix, and dilute with distilled water to the same volume as was used in subdivision (i) of this subparagraph. Place 2.0 milliliters in a 125-milliliter glass-stoppered Erlenmeyer flask, add 10 milliliters of 0.01 *N* iodine, allow to stand for 15 minutes, and titrate with 0.01 *N* sodium thiosulfate as directed in the iodometric assay procedure in § 141a.5 (d) (1). The total potency of the batch is satisfactory if it contains not less than 85 percent of that which it is represented to contain.

(2) *Procaine penicillin content (except for single-dose containers).* Make suitable dilutions of the solution prepared in subparagraph (1) (ii) of this paragraph to obtain approximately 60 units of procaine penicillin per milliliter. Determine the procaine penicillin content by the colorimetric procedure described in § 141a.32 (b) (3). The content of procaine penicillin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(3) *Buffered crystalline penicillin content*—(i) *Preparation of the solution for assay.* (*a*) Add the indicated amount of distilled water to the contents of a vial of the sample, and shake well. Withdraw one dose of the suspension with a hypodermic syringe and place in a 10-milliliter volumetric flask. Add 20-percent sodium sulfate solution almost to the mark, centrifuge sufficiently to see the meniscus, make to volume with 20-percent sodium sulfate solution, shake well, and centrifuge to obtain a clear or reasonably clear solution; or

(*b*) If the original product contains more than 600,000 units, place it in a 50-milliliter volumetric flask, add 20-percent sodium sulfate to the mark, shake well, place a 10-milliliter portion in a centrifuge tube, and centrifuge to obtain a reasonably clear solution.

(*c*) Dilute a 5.0-milliliter aliquot of the clear solution obtained in (*a*) or (*b*) of this subdivision with 1-percent phosphate buffer, pH 6.0, to give a solution for assay of approximately 2,000 units per milliliter.

(ii) *Iodometric assay for total penicillin in the solution for assay.* Determine the total quantity of penicillin in the solution for assay by the iodometric assay procedure described in § 141a.5 (d) (1).

(iii) *Colorimetric determination of procaine penicillin in the solution for assay.* Proceed as directed in § 141a.32 (b) (3). The content of procaine penicillin in the batch is satisfactory if it is not less than 85 percent of that which it is represented to contain.

(iv) The buffered crystalline penicillin in one dose of the product is calculated as follows:

$$A=(B-C)F,$$

where

A= the buffered crystalline penicillin content of the product.
B= the number of units of penicillin per milliliter as determined in subparagraph (3) (ii) of this paragraph.
C= the number of units of procaine penicillin per milliliter as determined in subparagraph (3) (iii) of this paragraph.
F= the appropriate dilution factor depending on the dilutions made in the preparation of the solution for assay.

The content of buffered crystalline penicillin is satisfactory if the batch contains 85 percent of the number of units per milliliter that it is represented to contain.

(4) *Benzathine penicillin content.* The sum of the procaine penicillin content determined under subparagraph (2) or (6) of this paragraph and the buffered crystalline penicillin content determined under subparagraph (3) of this paragraph, subtracted from the total potency determined in subparagraph (1) or (5) of this paragraph, represents the benzathine penicillin G content. The benzathine penicillin G content is satisfactory if it is not less than 85 percent of the number of units that it is represented to contain.

(5) *Total potency of a single-dose container.* Wash out the material remaining in the volumetric flask referred

to in subparagraph (3) (i) (*a*) of this paragraph, or combine the contents remaining in the 50-milliliter volumetric flask and in the centrifuge tube referred to in subparagraph (3) (i) (*b*) of this paragraph. Dissolve the material by adding 10 milliliters of 1 *N* NaOH for each 300,000 units of benzathine penicillin and allow to stand 15 minutes. Add 1 milliliter of 1.2 *N* HCl for each milliliter of 1 *N* NaOH and then dilute with distilled water to give a concentration of approximately 2,000 units per milliliter. Place 2.0 milliliters in a 125-milliliter glass-stoppered Erlenmeyer flask, add 10 milliliters of 0.01 *N* iodine, allow to stand for 15 minutes, and then titrate with 0.01 *N* sodium thiosulfate as directed in § 141a.5 (d) (1). For the blank determination prepare a separate sample as directed in subparagraph (3) (i) (*a*) or (*b*) of this paragraph and in the first sentence of this subparagraph, then dilute with 1 percent phosphate buffer, pH 6.0, to give a concentration of approximately 2,000 units per milliliter. The total potency of the one-dose container is equal to the sum of the number of units found in this assay (units per milliliter×volume) and the number of units found (units per milliliter ×volume) in the solution for assay in subparagraph (3) (ii) of this paragraph.

(6) *Procaine penicillin content of a single-dose container.* Make suitable dilutions of the NaOH-inactivated solution prepared in subparagraph (5) of this paragraph to obtain approximately 60 units of procaine penicillin per milliliter. Determine the procaine penicillin content (units per milliliter× volume) of this solution by the colorimetric procedure described under § 141a.32 (b) (3). To this value add the procaine penicillin content (units per milliliter×volume) of the solution for assay, as found in subparagraph (3) (iii) of this paragraph, to obtain the procaine penicillin content of the one-dose container. The content of procaine penicillin in the batch is satisfactory if it is not less than 85 percent of that which it is represented to contain.

(b) *Sterility.* Proceed as directed in § 141a.47 (b).

(c) *Pyrogens.* Proceed as directed in § 141a.47 (d).

(d) *Toxicity.* Proceed as directed in § 141a.47 (c).

(e) *Moisture.* Proceed as directed in § 141a.26 (e).

(f) *pH.* Proceed as directed in § 141a.47 (f).

§ 141a.62 *Benzathine penicillin G and procaine penicillin for aqueous injection*—(a) *Total potency, benzathine penicillin G content, procaine penicillin content.* Proceed as directed in § 141a.61 (a) (1), (2), and (4).

(b) *Sterility, toxicity, pyrogens.* Proceed as directed in § 141a.47 (b), (c), and (d).

(c) *pH.* Proceed as directed in § 141a.5 (b), using the undiluted aqueous suspension or the suspension prepared as directed in the labeling for the drug.

(d) *Moisture (dry mixture of the drug).* Proceed as directed in § 141a.26 (e).

§ 141a.63 *Penicillin - bacitracin - neomycin ointment; penicillin-bacitracin-neomycin in oil*—(a) *Potency*—(1) *Penicillin content; bacitracin content.* Proceed as directed in § 141a.37 (a).

(2) *Neomycin content.* Proceed as directed in § 141e.411 (a) (2) of this chapter, except that sufficient penicillinase is added to the sample under test to completely inactivate the penicillin present. Its content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.8 (b).

§ 141a.64 *Penicillin - streptomycin tablets, penicillin-dihydrostreptomycin tablets*—(a) *Potency*—(1) *Penicillin content.* Proceed as directed in § 141a.9 (a). Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(2) *Streptomycin content.* Proceed as directed in § 141a.36 (a) (2). Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(3) *Dihydrostreptomycin content.* Proceed as directed in § 141a.36 (a) (3). Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a).

§ 141a.65 *Procaine penicillin-streptomycin-neomycin in oil; procaine penicillin-dihydrostreptomycin-neomycin in oil; procaine penicillin-streptomycin-neomycin ointment; procaine penicillin-dihydrostreptomycin-neomycin ointment*—(a) *Potency*—(1) *Penicillin content, streptomycin content, dihydrostreptomycin content.* Proceed as directed in § 141a.38 (a) (1), (2), and (3), except use only the cup-plate method of assay for streptomycin and dihydrostreptomycin.

(2) *Neomycin content.* (i) If it contains streptomycin, proceed as directed in § 141e.410 (b) (1) of this chapter, except prepare the sample as directed in § 141a.49 (a) (2) (i) and (ii).

(ii) If it contains dihydrostreptomycin, proceed as directed in § 141e.410 (b) (1) of this chapter, except prepare the sample as follows: Place 1.0 milliliter of the sample in a separatory funnel containing approximately 50 milliliters of peroxide-free ether and extract with four successive 20-milliliter portions of distilled water. Make the combined aqueous extractions to 100 milliliters with distilled water. Transfer a 10-milliliter aliquot of the aqueous extract to a 25-milliliter volumetric flask and add 1.0 milliliter of 5-percent $Ba(OH)_2$—$8H_2O$. Using a test-tube clamp, suspend the open flask in a steam bath so that the mouth of the flask is slightly above the level of the steam bath. Heat with steam for 3 hours; remove, cool, add one drop of 1.0-percent phenolphthalein and neutralize dropwise with 1.0 *N* H_2SO_4. Make to volume with distilled water and pour a reasonable aliquot into an appropriate centrifuging tube. Centrifuge for 5 minutes at approximately 4,000 r. p. m. and decant. Pipette an appropriate volume for assay and accurately add sufficient 1.0 *M* potassium phosphate buffer pH 8.0 to provide, after addition of distilled water, a solution having a molarity of 0.1 percent with respect to the potassium phosphate buffer and containing 10 micrograms of neomycin per milliliter.

(iii) If it contains dihydrostreptomycin, the neomycin content may also be determined as follows: Place 1.0 milliliter of the sample in a separatory funnel containing 50 milliliters of peroxide-free ether and extract with four successive 20-milliliter portions of 0.1 *M* potassium phosphate buffer at pH 7.8 to 8.0. Make the combined aqueous extractions to 100 milliliters with the 0.1 *M* potassium phosphate buffer. Pipette an appropriate volume for assay and accurately add sufficient 0.1 *M* potassium phosphate buffer to provide a solution containing 10 micrograms of neomycin per milliliter. Proceed as directed in § 141e.410 (b) (1) of this chapter, except add sufficient penicillinase to completely inactivate the penicillin present, and use as the test organism the Food and Drug Administration dihydrostreptomycin-resistant strain of M. pyogenes var. aureus (P. C. I. 1209 R. D.), which is grown and maintained in media containing 1,000 micrograms of dihydrostreptomycin per milliliter of agar.

(b) *Moisture.* Using 1 milliliter as the test sample, proceed as directed in § 141a.7 (c).

§ 141a.66 *Capsules procaine penicillin in oil*—(a) *Potency.* Proceed as directed in § 141a.1, except paragraph (i) of that section, and in lieu of the directions in § 141a.1 (d) prepare the sample as follows: Place 12 capsules in a blending jar containing 40 milliliters of absolute alcohol and 200 milliliters of distilled water. After blending for 1 minute with a high-speed blender, add 260 milliliters of distilled water. Blend again for 1 minute and make the proper estimated dilutions in 1-percent phosphate buffer at pH 6.0. Its potency is satisfactory if it contains not less than 85 percent of the number of units per capsule that it is represented to contain.

(b) *Moisture.* Using an accurately weighed sample of approximately 1 gram of the capsule contents, proceed as directed in § 141a.7 (c).

§ 141a.67 *Procaine penicillin and benzathine penicillin G in streptomycin sulfate solution; procaine penicillin and benzathine penicillin G in dihydrostreptomycin sulfate solution (procaine penicillin and benzathine penicillin G in crystalline dihydrostreptomycin sulfate solution)*—(a) *Potency*—(1) *Total potency and procaine penicillin content.* Proceed as directed in § 141a.61 (a) (1) and (2), except that in the iodometric assay one drop of 1.2 *N* HCl is added to the blank immediately, before the addition of the 0.01 *N* iodine.

(2) *Benzathine penicillin G content.* The difference between the total penicillin potency and the procaine penicillin content determined under subparagraph (1) of this paragraph represents the benzathine penicillin G content. The

benzathine penicillin G content is satisfactory if it is not less than 85 percent of that which it is represented to contain.

(3) *Streptomycin content.* Proceed as directed in § 141b.101 (j) and (k) of this chapter.

(4) *Dihydrostreptomycin content.* Proceed as directed in § 141b.108 (a) of this chapter.

(b) *Sterility.* Proceed as directed in § 141a.47 (b), except that no control tube is used in the test for bacteria.

(c) *Toxicity.* Proceed as directed in § 141a.39 (c).

(d) *Pyrogens.* Proceed as directed in § 141a.39 (d).

(e) *pH.* Proceed as directed in § 141a.5 (b), using the undiluted aqueous suspension.

§ 141a.68 *Benzathine penicillin G and streptomycin, benzathine penicillin G and dihydrostreptomycin*—(a) *Potency*—(1) *Content of benzathine penicillin G.* Proceed as directed in § 141a.47 (a). Its content of benzathine penicillin G is satisfactory if it contains not less than 90 percent of the number of units that it is represented to contain.

(2) *Streptomycin content.* Proceed as directed in § 141b.101 (j) of this chapter. Its content of streptomycin is satisfactory if it contains not less than 90 percent of the number of grams that it is represented to contain.

(3) *Dihydrostreptomycin content.* Proceed as directed in § 141b.108 (a) of this chapter. Its content of dihydrostreptomycin is satisfactory if it contains not less than 90 percent of the number of grams that it is represented to contain.

(b) *Sterility.* Use the entire contents of single-dose containers or the equivalent of approximately 0.5 gram (combined activity) for each multiple-dose container, and proceed as directed in § 141a.47 (b), except that no control tube is used in the test for bacteria.

(c) *Moisture.* Proceed as directed in § 141a.26 (e).

(d) *Toxicity, pyrogens, pH.* Proceed as directed in § 141a.39 (c), (d), and (f).

§ 141a.69 *Crystalline penicillin G oral suspension, crystalline penicillin G sodium oral suspension, potassium penicillin G oral suspension*—(a) *Potency.* Proceed as directed in § 141a.1, except § 141a.1 (i), and in lieu of the directions in § 141a.1 (d), prepare the sample as follows: By means of a hypodermic syringe, introduce 5 milliliters of the well-shaken test sample into a high-speed blender containing 244 milliliters of 1-percent phosphate buffer at pH 6.0 and 1.0 milliliter of a 10-percent aqueous solution of polysorbate 80. Blend the mixture for 3 to 5 minutes. Make the proper estimated dilutions in 1-percent phosphate buffer at pH 6.0. Its potency is satisfactory if it contains not less than 85 percent of the number of units per milliliter that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.7 (c).

§141a.70 *Tablets benzathine penicillin G and crystalline penicillin*—(a) *Potency*—(1) *Total potency.* Proceed as directed in § 141a.9 (a) (2). Its total potency is satisfactory if it contains not less than 85 percent of the number of units per tablet that it is represented to contain.

(2) *Crystalline penicillin content.* Place 5 tablets in a blending jar and add thereto sufficient distilled water to give a concentration of 5,000 units of crystalline penicillin per milliliter. Blend for 2 minutes with a high-speed blender, filter, remove a 10-milliliter aliquot of the filtrate and dilute to 25 milliliters with 1.0 percent phosphate buffer at pH 6.0. Remove a 2-milliliter aliquot of this solution and assay by the iodometric assay procedure described in § 141a.5 (d) (1). Its content of crystalline penicillin is satisfactory if it contains not less than 85 percent of the number of units per tablet that it is represented to contain.

(3) *Benzathine penicillin G content.* The benzathine penicillin G content of the batch is the difference between the total potency as determined by the method described in subparagraph (1) of this paragraph and the content of crystalline penicillin as determined by the method prescribed in subparagraph (2) of this paragraph. Its content of benzathine penicillin G is satisfactory if it contains not less than 85 percent of the number of units per tablet that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.26 (e).

§ 141a.71 *Penicillin - streptomycin powder, penicillin-dihydrostreptomycin powder*—(a) *Potency*—(1) *Penicillin content.* Use an accurately weighed sample of approximately 1 gram and proceed as directed in § 141a.1, except paragraph (i) of that section. The penicillin content of the powder is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(2) *Streptomycin content.* Use an accurately weighed sample of approximately 1 gram and proceed as directed in § 141a.36 (a) (2). The streptomycin content of the powder is satisfactory if it contains not less than 85 percent of the number of milligrams of activity that it is represented to contain.

(3) *Dihydrostreptomycin content.* Use an accurately weighed sample of approximately 1 gram and proceed as directed in § 141a.36 (a) (3). The dihydrostreptomycin content of the powder is satisfactory if it contains not less than 85 percent of the number of milligrams of activity that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a).

§ 141a.72 *Dibenzylamine penicillin G (dibenzylamine penicillin G salt)*—(a) *Potency.* Proceed as directed in § 141a.26 (a).

(b) *Sterility.* Proceed as directed in § 141a.2.

(c) *Pyrogens.* Proceed as directed in § 141a.3, except use physiological salt solution as the diluent.

(d) *Toxicity.* Proceed as directed in § 141a.4, except use physiological salt solution as the diluent, and inject 0.25 milliliter of a solution containing 4,000 units per milliliter.

(e) *Moisture.* Proceed as directed in § 141a.26 (e).

(f) *pH.* Proceed as directed in § 141a.5 (b), using a saturated aqueous solution prepared by adding 300 milligrams per milliliter.

(g) *Microscopical test for crystallinity.* Proceed as directed in § 141a.5 (c).

(h) *Penicillin G content.* Proceed as directed in § 141a.26 (h), using the following formula for calculating the percent of dibenzylamine penicillin G:

$$\text{Percent of dibenzylamine penicillin G} = \frac{N\text{-ethyl piperidine penicillin precipitate} \times 245.5}{\text{Weight of sample in milligrams}}$$

§ 141a.73 *Dibenzylamine penicillin and potassium penicillin powder, buffered*—(a) *Total potency.* Proceed as directed in § 141a.1, using 5 milliliters of the preparation, reconstituted as directed in the labeling.

(b) *Potassium penicillin content.* Centrifuge approximately 10 milliliters of the reconstituted preparation to obtain a clear solution and proceed as directed in § 141a.1, using 5 milliliters of the clear solution. The potency of the clear solution is regarded as the potassium penicillin content. The content of potassium penicillin is satisfactory if it is not less than 85 percent of that which it is represented to contain.

(c) *Dibenzylamine penicillin content.* The difference between the total potency as determined by paragraph (a) of this section and the potassium penicillin as determined by paragraph (b) of this section represents the amount of dibenzylamine penicillin present. The content of dibenzylamine penicillin is satisfactory if it is not less than 85 percent of that which it is represented to contain.

(d) *Moisture.* Proceed as directed in § 141a.26 (e).

§ 141a.74 *Dibenzylamine penicillin and streptomycin in oil, dibenzylamine penicillin and dihydrostreptomycin in oil*—(a) *Potency*—(1) *Penicillin content.* Proceed as directed in § 141a.27 (a), except the last sentence thereof. Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units per milliliter that it is represented to contain.

(2) *Streptomycin content.* Using 1.0 milliliter as the test sample, proceed as directed in § 141a.35 (a) (2). Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per milliliter that it is represented to contain.

(3) *Dihydrostreptomycin content.* Using 1.0 milliliter as the test sample, proceed as directed in § 141a.35 (a) (3). Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per milliliter that it is represented to contain.

(b) *Moisture.* Using 1.0 milliliter as the test sample, proceed as directed in § 141a.7 (c).

§ 141a.75 *Hydrabamine penicillin G*—(a) *Potency.* Proceed as directed in § 141a.1, except if the bioassay method is used prepare the sample as follows: Dissolve an accurately weighed sample in methanol and dilute with methanol to 1,000 units per milliliter (estimated). By means of a volumetric pipette, add a 1.0-milliliter aliquot to a 1,000-milliliter volumetric flask containing approximately 300 milliliters of 1-percent phosphate buffer, pH 6.0, constantly swirling the flask during the addition. Make to a volume of 1,000 milliliters with 1-percent phosphate buffer, pH 6.0. If the iodometric method is used, accurately weigh 30–50 milligrams of the sample to be tested in a 50-milliliter Erlenmeyer flask and dissolve in sufficient chloroform U. S. P. to give a concentration of 2.0 milligrams per milliliter. Pipette 2.0 milliliters of this solution into a 125-milliliter glass-stoppered Erlenmeyer flask, add 10 milliliters of 0.01 N I_2 and titrate immediately with 0.01 N $Na_2S_2O_3$ for the blank determination. Toward the end of the titration add 1 drop of starch solution or about 5.0 milliliters of CCl_4. Continue the titration by the addition of 0.01–0.02-milliliter portions of 0.01 N $Na_2S_2O_3$, shaking vigorously after each addition. The end point is reached when the blue color of the starch-iodine complex is discharged or when the CCl_4 layer becomes colorless. Prepare the solution of inactivated penicillin as follows: To 10 milliliters of the original chloroform solution add 10 milliliters of 1 N NaOH and shake well immediately and 5 minutes later. Fifteen minutes after the initial shaking, pipette 2.0 milliliters of the upper NaOH layer into a 125-milliliter glass-stoppered Erlenmeyer flask, add 2.0 milliliters of 1.2 N HCl and 10 milliliters of 0.01 N I_2. Stopper the flask. After 15 minutes, titrate the excess iodine with 0.01 $Na_2S_2O_3$.

Units of hydrabamine penicillin G per milligram

$$=\frac{\text{Difference in titers} \times \text{potency of F. D. A. working standard in units per milligram}}{4 \times F}$$

where F=the number of milliliters of 0.01 N I_2 absorbed for each 1.0 milligram of the Food and Drug Administration sodium penicillin G working standard.

(b) *Toxicity.* Proceed as directed in § 141a.4, except use physiological salt solution as the diluent and inject 0.25 milliliter of a suspension containing 4,000 units per milliliter.

(c) *Moisture.* Proceed as directed in § 141a.26 (e).

(d) *pH.* Proceed as directed in § 141a.5 (b), using a saturated aqueous solution prepared by adding approximately 60 milligrams per milliliter.

(e) *Microscopical test for crystallinity.* Proceed as directed in § 141a.5 (c).

(f) *Penicillin G content.* Accurately weigh a glass weighing bottle of approximately 10-milliliter capacity together with its top, a stirring rod, and a medium-porosity immersion filter stick. Transfer to the weighing bottle approximately 225 milligrams of the sample to be tested and reweigh. Add 1.5 milliliters of pyridine and stir until solution is complete. Add 0.25 milliliter of N-ethylpiperidine and stir until precipitation begins. When precipitation is complete, dilute with 2.5 milliliters of petroleum ether, stir well, and allow to stand for 15 minutes. Attach the filter stick to a vacuum line equipped with a suitable trap and withdraw the liquid from the precipitate. Add 2.5 milliliters of petroleum ether to the precipitate and withdraw the liquid from the precipitate. Repeat the procedure with two more 2.5-milliliter portions of petroleum ether. Leave the stirring rod and the filter stick in the bottle, dry for 30 minutes in a vacuum desiccator, stopper, and weigh.

Percent of hydrabamine penicillin G

$$=\frac{\text{Milligrams of } N\text{-ethyl piperidine penicillin precipitate} \times 141.4}{\text{Weight of sample in milligrams}}$$

(g) *Extinction coefficient.* Accurately weight approximately 100 milligrams of the sample, dissolve in absolute methanol, and make to 100 milliliters. Determine the extinction coefficient of the sample at the absorption peak at 276 millimicrons, using a suitable ultraviolet spectrophotometer and 1-centimeter quartz cells. Set the instrument to 100-percent transmission with absolute methanol. If a recording spectrophotometer is used, record the ultraviolet absorption spectrum from 240-300 millimicrons. If a nonrecording spectrophotometer is used, determine the absorbancy of the solution at the 276-millimicron absorption peak, using a slit width of 0.4 millimeter or less. (The exact position of the peak should be determined for the particular instrument used.) Calculate the $E^{1\%}_{1\,\text{cm.}}$ value of the sample at the absorption peak at 276 millimicrons.

§ 141a.76 *Hydrabamine penicillin G oral suspension*—(a) *Potency.* Proceed as directed in § 141a.1, except if the bioassay method is used prepare the sample as follows: Place 1.0 milliliter of the sample to be tested in a 100-milliliter volumetric flask and dilute to volume with methanol. By means of a volumetric pipette add a 1.0-milliliter aliquot of this solution to a sufficient volume of 1-percent phosphate buffer pH 6.0 to give a solution having a concentration of 1 unit per milliliter (constantly swirling the flask during the addition). If the iodometric method is used, dilute 1.0 milliliter of the sample with sufficient 1-percent phosphate buffer pH 6.0 to produce a suspension containing 2,000 units per milliliter (estimated). Mix and pipette 2.0 milliliters into a 125-milliliter glass-stoppered Erlenmeyer flask. Add 10 milliliters of 0.01 N I_2 and titrate immediately with 0.01 N $Na_2S_2O_3$ for the blank determination. Dilute a second 1.0-milliliter portion of the sample with 1 N NaOH to produce a suspension containing 2,000 units per milliliter (estimated) and add approximately half that amount of chloroform U. S. P. Shake immediately and again after 5 minutes. Fifteen minutes after the initial shaking, pipette 2.0 milliliters of the upper NaOH layer into a 125-milliliter glass-stoppered Erlenmeyer flask and add 2.0 milliliters of 1.2 N HCl and 10 milliliters of 0.01 N I_2 After 15 minutes titrate the excess iodine with 0.01 N $Na_2S_2O_3$.

Units of penicillin per milliliter of suspension

$$=\frac{\text{Difference in titers} \times \text{potency of F. D. A. working standard in units per milligram} \times \text{volume of 2,000 units per milliliter suspension}}{F \times 2}$$

where F=the number of milliliters of 0.01 N I_2 absorbed by 1.0 milligram of the Food and Drug Administration sodium penicillin G working standard.

(b) *pH.* Proceed as directed in § 141a.5 (b), using the undiluted aqueous suspension.

§ 141a.77 *Capsules crystalline penicillin G (capsules crystalline penicillin G potassium, capsules crystalline penicillin G sodium)*—(a) *Potency.* Use the contents of 12 capsules and proceed as directed in § 141a.1, except § 141a.1 (i), and except if it contains a vegetable oil, prepare the sample as follows: Place 12 capsules in a blending jar containing 1.0 milliliter of a 10-percent aqueous solution of polysorbate 80 and sufficient 1-percent phosphate buffer, pH 6.0, to give a volume of 250 milliliters. Using a high-speed blender, blend for 3 to 5 minutes, then add 250 milliliters of buffer and blend for an additional minute. Make further dilutions to 1 unit per milliliter (estimated) with 1-percent phosphate buffer, pH 6.0. The average potency of capsules crystalline penicillin G is satisfactory if it is not less than 85 percent of the number of units per capsule they are represented to contain.

(b) *Moisture.* Use the contents of 4 capsules and proceed as directed in § 141a.5 (a), except if it contains a vegetable oil proceed as directed in § 141a.7 (c).

§ 141a.78 *Benzathine penicillin G in oil*—(a) *Potency.* Proceed as directed in § 141a.1, except paragraph (i) of that section, and in lieu of the directions in § 141a.1 (d) prepare the sample as follows: Place a representative quantity (usually 1.0 milliliter) of a multiple-dose container, or the entire contents of a single-dose container, in a blending jar containing sufficient dimethyl formamide (previously adjusted to a pH of 6.5±0.5 with concentrated H_2SO_4) to give a final volume of 100 milliliters. Using a high-speed blender, blend the mixture for 2 minutes and then make the proper estimated dilutions in a 1.0-percent phosphate buffer at pH 6.0. The potency is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(b) *Sterility.* Proceed as directed in § 141a.47 (b).

(c) *Moisture.* Proceed as directed in § 141a.7 (c).

§ 141a.79 *Benzathine penicillin G and procaine penicillin G in oil*—(a) *Potency* -(1) *Total penicillin content.* Proceed as directed in § 141a.78 (a). The total potency is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(2) *Procaine penicillin content.* Using an appropriate dilution of the solution prepared in subparagraph (1) of this paragraph, proceed as directed in § 141a.32 (b) (3). The procaine penicillin content is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(3) *Benzathine penicillin G content.* The benzathine penicillin G content is the difference between the total penicillin content as determined in subparagraph (1) of this paragraph and the procaine penicillin content as determined in subparagraph (2) of this paragraph. The benzathine penicillin G content is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(b) *Sterility.* Proceed as directed in § 141a.47 (b).

(c) *Moisture.* Proceed as directed in § 141a.7 (c).

§ 141a 80 *Benzathine penicillin G-procaine penicillin G-streptomycin in oil; benzathine penicillin G-procaine penicillin G-dihydrostreptomycin in oil*—(a) *Potency*—(1) *Total penicillin content.* Proceed as directed in § 141a.79 (a) (1). The total penicillin content is satisfactory if it contains not less than 85 percent of the number of units per milliliter that it is represented to contain.

(2) *Procaine penicillin content.* Proceed as directed in § 141a.79 (a) (2). The procaine penicillin content is satisfactory if it contains not less than 85 percent of the number of units per milliliter that it is represented to contain.

(3) *Benzathine penicillin G content.* Proceed as directed in § 141a.79 (a) (3). The benzathine penicillin G content is satisfactory if it contains not less than 85 percent of the number of units per milliliter that it is represented to contain.

(4) *Streptomycin content.* Using a representative quantity (usually 1.0 milliliter) of a multiple-dose container, or the entire contents of a single-dose container, proceed as directed in § 141a.35 (a) (2). The streptomycin content is satisfactory if it contains not less than 85 percent of the number of milligrams per milliliter that it is represented to contain.

(5) *Dihydrostreptomycin content.* Using a representative quantity (usually 1.0 milliliter) of a multiple-dose container, or the entire contents of a single-dose container, proceed as directed in § 141a.35 (a) (3). The dihydrostreptomycin content is satisfactory if it contains not less than 85 percent of the number of milligrams per milliliter that it is represented to contain.

(b) *Sterility.* Proceed as directed in § 141a.47 (b).

(c) *Moisture.* Proceed as directed in § 141a.7 (c).

§ 141a.81 *Penicillin V (phenoxymethyl penicillin)*—(a) *Potency.* Proceed as directed in § 141a.1, except use the penicillin V working standard as the standard of comparison. If the iodometric assay method is used, proceed as directed in § 141a.5 (d) (1), except determine the factor F as the number of milliliters of 0.01 *N* I_2 absorbed by 1.0 milligram of penicillin V working standard.

$$\text{Units of penicillin V per milligram}=\frac{\text{Difference in titers}\times\text{potency of FDA penicillin V working standard in units per milligram}}{\text{Milligrams in 2.0 milliliters tested}\times F}$$

(b) *Toxicity.* Proceed as directed in § 141a.4, except use physiological salt solution as the diluent, and inject 0.5 milliliter of a solution containing 2,000 units per milliliter.

(c) *Moisture.* Proceed as directed in § 141a.26 (e).

(d) *pH.* Proceed as directed in § 141a.5 (b), using a saturated aqueous solution prepared by adding 5 milligrams per milliliter.

(e) *Microscopical test for crystallinity.* Proceed as directed in § 141a.5 (c).

(f) *Penicillin V content.* Accurately weigh approximately 50 milligrams of the sample, dissolve in absolute methanol, and make to 100 milliliters with absolute methanol. Determine the absorbance of the sample at the absorption peak at 276 mμ, using a suitable ultraviolet spectrophotometer and quartz cells. Set the instrument to 100-percent transmission with absolue methanol. If a recording spectrophotometer is used, record the ultraviolet absorption spectrum from 240–290 mμ. If a nonrecording spectrophotometer is used, determine the absorbance (or a solution containing 20 milligrams per 100 milliliters) at the 276 mμ absorption peak, using a slit width of 0.5 millimeter or less. (The exact position of the peak should be determined for the particular instrument used.)

$$\text{Percent penicillin V}=\frac{\text{Absorbance}\times 100{,}000}{\text{Milligrams of sample per 100 milliliters}\times 34},$$

where 34 is the $E\frac{1\%}{1\text{ cm.}}$ (specific absorbance) of the pure penicillin V.

§ 141a.84 *Tablets benzathine penicillin G and penicillin V*—(a) *Potency*—(1) *Total penicillin content.* Accurately weigh 6 tablets and grind them to a fine powder. Assay this powder by the iodometric method described in § 141a.5 (d) (1), except in preparing the blank solution accurately weigh a portion of the powder equivalent to approximately 200,000 units of penicillin and make a suspension in 1-percent phosphate buffer, pH 6.0, with a volume of 100 milliliters. Shake well, pipette 2.0 milliliters into a 125-milliliter glass-stoppered Erlenmeyer flask, add 10.0 milliliters of 0.01 *N* iodine and immediately titrate with 0.01 *N* $NA_2S_2O_3$. In preparing the solution for inactivation, accurately weigh a portion of the powder equivalent to 200,000 units of penicillin and place in a 100-milliliter volumetric flask. Add 20 milliliters of 0.5 *N* NaOH and mix well. Allow to stand for 15 minutes, then add 10 milliliters of 1.2 *N* HCl, and make to volume with distilled water. Pipette a 2.0-milliliter aliquot into a 125-milliliter glass-stoppered Erlenmeyer flask and add 10.0 milliliters of 0.01 *N* iodine. Allow to stand for 15 minutes and then titrate the excess iodine with 0.01 *N* $Na_2S_2O_3$. Penicillin G is used as the standard of comparison. The total penicillin content is satisfactory if it is not less than 85 percent of that which it is represented to contain.

(2) *Penicillin V content.* Place in a 125-milliliter separatory funnel an accurately weighed quantity of finely ground tablet powder equivalent to approximately 20 milligrams (33,900 units) of penicillin V. Add 50.0 milliliters of spectrophotometric grade chloroform and 1 milliliter of 1:4 H_3PO_4. Shake well for 2 minutes. Allow the layers to separate, filter the lower chloroform layer through a cotton pledget, and collect the clear chloroform solution. Determine the absorbance of the chloroform solution at the absorption peak at 276 mμ, using a suitable ultraviolet spectrophotometer and 1-centimeter quartz cells. Set the instrument to 100-percent transmission with chloroform. If a recording spectrophotometer is used, record the ultraviolet absorption spectrum from 250–290 mμ. If a nonrecording spectrophotometer is used, the original sample used should be equivalent to approximately 10 milligrams of penicillin V. Determine the absorbance of the solution at the 276 mμ absorption peak. (The exact position of the peak should be determined for the particular instrument used.) Calculate the amount of penicillin V per tablet as follows:

$$\text{Penicillin V units per tablet} = \frac{{}^{A}276\ \text{m}\mu \times \text{average weight of each tablet} \times 1{,}695{,}000}{\text{Weight of powder taken} \times 2 \times E_{vs}},$$

where $^{A}276$ mμ = observed absorbance of chloroform solution,

E_{vs} = specific absorbance ($E^{1\%}_{1\,\text{cm.}}$) of penicillin V standard in chloroform similarly treated.

The penicillin V content is satisfactory if it is not less than 85 percent of that which it is represented to contain.

(3) *Penicillin G content.* The penicillin G content of the batch is the difference between the total penicillins determined by the method described in subparagraph (1) of this paragraph and the penicillin V content determined by the method described in subparagraph (2) of this paragraph. The penicillin G content is satisfactory if it is not less than 85 percent of that which it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.26 (e).

§ 141a.85 *Capsules penicillin V*—(a) *Potency.* Dissolve the contents of 12 capsules in 1-percent phosphate buffer, pH 6.0, and proceed as directed in § 141a.1, except use the penicillin V working standard as the standard of comparison. The average potency of capsules penicillin V is satisfactory if it is not less than 85 percent of the number of units per capsule they are represented to contain.

(b) *Moisture.* Use the contents of 4 capsules and proceed as directed in § 141a.26 (e).

§ 141a.86 *Procaine penicillin-streptomycin-polymyxin in oil; procaine penicillin-dihydrostreptomycin-polymyxin in oil*—(a) *Potency*—(1) *Penicillin content.* Proceed as directed in § 141a.8 (a). Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units per milliliter that it is represented to contain.

(2) *Streptomycin content.* Proceed as directed in § 141b.129 (a) (1) of this chapter, except inactivate the penicillin in the combined extractives with sufficient penicillinase at 37° C. for 30 minutes. Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per milliliter that it is represented to contain.

(3) *Dihydrostreptomycin content.* Proceed as directed in subparagraph (2) of this paragraph, using the dihydrostreptomycin working standard as a standard of comparison. Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram that it is represented to contain.

(4) *Polymyxin content.* Proceed as directed in § 141b.112 (b) (1) of this chapter, with the following exceptions:

(i) In lieu of the directions for the preparation of the sample described in § 141b.112 (b) (1) (vii) of this chapter, prepare the sample as follows: Place a convenient sized representative quantity of the sample in a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake the sample and ether until homogeneous. Add 25 milliliters of 10-percent potassium phosphate buffer, pH 6.0, containing 2 grams of K_2HPO_4 and 8 grams of KH_2PO_4 in each 100 milliliters, and shake. Remove the buffer layer and repeat the extraction with 25-milliliter portions of buffer at least three times and any additional times that may be necessary to insure complete extraction of the antibiotic. Combine the extractives and inactivate the penicillin with sufficient penicillinase at 37° C. for 30 minutes. Make the proper estimated dilutions in 10-percent potassium phosphate buffer, pH 6.0, to give a concentration of 10 units per milliliter (estimated).

(ii) The standard curve is prepared in the following concentrations: 6, 7, 8, 9, 10, 11, 12, 13, 14, and 15 units per milliliter in 10-percent potassium phosphate buffer, pH 6.0. The 10 units per milliliter concentration is used as the reference point. Its content of polymyxin is satisfactory if it contains not less than 85 percent of the number of units per milliliter that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.8 (b).

PART 141b—STREPTOMYCIN (OR DIHYDROSTREPTOMYCIN) AND STREPTOMYCIN- (OR DIHYDROSTREPTOMYCIN-) CONTAINING DRUGS; TESTS AND METHODS OF ASSAY

Sec.
141b.101 Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; potency.
141b.102 Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; sterility.
141b.103 Streptomycin sulfate, streptomycin hydrochloride, streptomycin trihydrochloride calcium chloride; phosphate, streptomycin trihytoxicity.
141b.104 Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; pyrogens.
141b.105 Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; histamine.
141b.106 Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride.
141b.107 Streptomycin ointment, dihyrostreptomycin ointment; potency.
141b.108 Dihydrostreptomycin sulfate, crystalline dihydrostreptomycin sulfate, dihydrostreptomycin hydrochloride.
141b.109 Streptomycin tablets, dihydrostreptomycin tablets.
141b.110 Streptomycin for topical use.
141b.111 Streptomycin sulfate solution, dihydrostreptomycin sulfate solution, crystalline dihydrostreptomycin sulfate solution.
Sec.
141b.112 Streptomycin - polymyxin - bacitracin tablets.
141b.113 Streptomycin syrup, streptomycin and kaolin in gel, dihydrostreptomycin syrup, dihydrostreptomycin and kaolin in gel; potency.
141b.114 Streptomycin - bacitracin - polymyxin gauze pads.
141b.115 Streptomycin otic with antifungal agent, dihydrostreptomycin otic with antifungal agent.
141b.116 Streptomycin - kaolin - pectin-aluminum hydroxide gel powder veterinary, dihydrostreptomycin - kaolin - pectin - aluminum hydroxide gel powder veterinary.
141b.117 Streptomycin for inhalation therapy, dihydrostreptomycin for inhalation therapy.
141b.118 Dihydrostreptomycin - streptomycin sulfates.
141b.119 Streptomycin sulfate oral veterinary.
141b.120 Streptomycin sulfate powder oral veterinary; streptomycin sulfate granules oral veterinary.
141b.121 Streptomycylidene isonicotinyl hydrazine sulfate.
141b.122 Dihydrostreptomycin - streptomycin sulfates solution.
141b.123 Streptomycin - penicillin - sulfonamide with kaolin and pectin, dihydrostreptomycin - penicillin-sulfonamide with kaolin and pectin.
141b.124 Streptomycin hydrochloride solution oral veterinary; streptomycin sulfate solution oral veterinary.
141b.125 Dihydrostreptomycin - streptomycin sulfates with isonicotinic acid hydrazide.
141b.126 Streptomycin-erythromycin ointment.
141b.127 Streptomycin - chlortetracycline-chloramphenicol-bacitracin dental cement; dihydrostreptomycin - chlortetracycline - chloramphenicol - bacitracin dental cement.
141b.128 Streptomycin-sodium sulfathiazole solution veterinary; dihydrostreptomycin-sodium sulfathiazole solution veterinary.
141b.129 Streptomycin-polymyxin-neomycin ointment; dihydrostreptomycin-polymyxin-neomycin ointment.

AUTHORITY: §§ 141b.101 to 141b.129 issued under sec. 701, 52 Stat. 1055; 21 U. S. C. 371. Interpret or apply sec. 507, 59 Stat. 463, as amended; 21 U. S. C. 357.

§ 141b.101 *Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; potency*—(a) *Cylinders (cups).* Use cylinders described under § 141a.1 (a) of this chapter.

(b) *Culture media.* Using ingredients that conform to the standards prescribed by the U. S. P. or N. F., make nutrient agar for the seed and base layers:

Beef extract	1.5 gm.
Yeast extract	3.0 gm.
Peptone	6.0 gm.
Agar	15.0 gm.
Distilled water q. s.	1,000.0 ml.

pH 7.8 to 8.0 after sterilization.

(c) *Working standard.* Keep the working standard (obtained from the Food and Drug Administration) at room temperature in tightly stoppered vials, which in turn are kept in larger stoppered vials containing anhydrous magnesium perchlorate. Dry an appropriate amount of the working standard as described in § 141a.5 (a) of this chapter (the moisture-free working standard has a potency of 780 micrograms per milligram). Dissolve the weight of dry working standard obtained in 0.05 *M* potassium phosphate buffer (pH 6.0). Keep this stock solution at a temperature of about 15° C.; do not use it later than 30 days after it is made.

(d) *Standard curve.* Prepare daily in 0.10 *M* potassium phosphate buffer (pH 7.8 to 8.0) from the stock solution described in paragraph (c) of this section, concentrations of 0.6, 0.7, 0.8, 0.9, 1.0, 1.1, 1.2, 1.3, 1.4, and 1.5 micrograms per milliliter solutions. A total of 27 plates is used in the preparation of the standard curve, three plates for each solution except the 1.0 mcg./ml. solution. The latter concentration is used as the reference point and is included on each plate. On each of three plates fill 3 cylinders with the 1.0 mcg./ml. standard and the other 3 cylinders with the concentration under test. Thus there will be 81 one microgram determinations and 9 determinations for each of the other points on the curve. After the plates have incubated read the diameters of the circles of inhibition. Average the readings of the 1.0 mcg./ml. concentration and the readings of the point tested for each set of 3 plates and average also all 81 readings of the 1.0 mcg./ml. concentration. The average of the 81 readings of the 1.0 mcg./ml. concentration is the correction point for the curve. Correct the average value obtained for each point to the figure it would be if the 1.0 mcg./ml. reading for that set of three plates were the same as the correction point. Thus, if in correcting the 0.8 unit concentration, the average of the 81 readings of the 1.0 mcg./ml. concentration is 16.5 mm. and the average of the 1.0 mcg./ml. concentration of this set of 3 plates is 16.3 mm. the correction is 0.2 mm. If the average readings of the 0.8 mcg./ml. concentration of these same 3 plates is 15.9 millimeters the corrected value is then 16.1 millimeters. Plot these corrected values including the average of the 1.0 mcg./ml. concentration on 2 cycle semilog paper using the concentration in mcg./ml. as the ordinate (the logarithmic scale) and the diameter of the zone of inhibition as the abscissa. Draw the standard curve through these points. The ten points selected to determine the curve are arbitrary and should be so chosen that the limits of the curve will fill the needs of the laboratory. However, the potency of the sample under test should fall in the interval of from 60 percent to 150 percent of the correction point of the standard curve.

(e) *Preparation of sample.* Dissolve volumetrically in sterile, distilled water, the sample to be tested to make a convenient stock solution. Further dilute this solution volumetrically to contain 100 micrograms of streptomycin base (estimated) per milliliter. Transfer 1.0 milliliter of this 100 micrograms (estimated) per milliliter solution to a 100-milliliter flask and make up to volume with 0.10 *M* potassium phosphate buffer (pH 7.8 to 8.0). Use this last dilution in the assay for potency.

(f) *Preparation of suspensions*—(1) *Preparation of spore suspensions.* The test organism is Bacillus subtilis (American Type Culture Collection 6633). Maintain the test organism on nutrient agar prepared as described in § 141a.1 (b) (1) of this chapter. Prepare a spore suspension by one of the following methods:

(i) Grow the organism for 1 week at 37° C. in a number of Roux bottles each containing 300 milliliters of nutrient agar prepared as described in § 141a.1 (b) (1) of this chapter. Suspend the spores in sterile distilled water and heat for 30 minutes at 65° C. Wash the spore suspension three times with sterile distilled water, heat again for 30 minutes at 65° C. and resuspend in sterile distilled water; or

(ii) Grow the organism for 5 days at 37° C. in a Roux bottle containing 300 milliliters of agar medium described in § 141a.1 (b) (1) of this chapter, but modified by the addition of 300 milligrams of $MnSO_4 \cdot H_2O$ per liter. Suspend the growth in 50 milliliters of sterile isotonic saline solution, centrifuge, and decant the supernatant liquid. Reconstitute the sediment and heat-shock the suspension by heating for 30 minutes at 70° C. Maintain the spore suspension at approximately 15° C. Determine by appropriate tests the quantity of spore suspension to be added to each 100 milliliters of agar for the secondary layer that will give sharp, clear zones of inhibition.

(2) *Preparation of vegetative suspension.* If a suspension of the test organism is to be used in lieu of the spore suspensions described in subparagraph (1) of this paragraph, prepare such suspension as follows: Using 2.0 milliliters of sterile distilled water, wash the organism from an agar slant (which has been incubated for 24 hours at 37° C.) onto the agar surface of a Roux bottle containing 300 milliliters of nutrient agar prepared as described in § 141a.1 (b) (1) of this chapter. Incubate for 24 hours at 37° C. Suspend the resultant growth in 50 milliliters of sterile distilled water and homogenize the suspension. Determine by appropriate tests the quantity of the vegetative suspension to be added to each 100 milliliters of agar for the secondary layer that will give sharp, clear zones of inhibition.

(g) *Preparation of plates.* Add 21 milliliters of agar described in paragraph (b) of this section to each Petri dish (20×100 millimeters). Melt the agar to be used for the secondary layer, cool to 55° to 60° C. and add the spore suspension prepared in paragraph (f) of this section. Mix thoroughly and add 4 milliliters to each of the plates containing the 21 milliliters of the uninoculated agar. Tilt the plates back and forth to spread the inoculated agar evenly over the surface.

(h) *Plate assay.* Place six cylinders on the inoculated agar surface so that they are at approximately 60° intervals on 2.8-centimeter radius. Use three plates for each sample. Fill three cylinders on each plate with the 1.0 mcg./ml. standard and three cylinders with the 1.0 mcg./ml. (estimated) sample, alternating standard and sample. Incubate the plates for 16 to 18 hours at 37° C. and measure the diameter of each circle of inhibition.

(i) *Estimation of potency.* Average the zone readings of the standard and average the zone readings of the sample on the three plates used. If the sample gives a larger average zone size than the average of the standard, add the difference between them to the 1.0 microgram zone size of the standard curve. If the average sample value is lower than the standard value, subtract the difference between them from the 1.0 microgram value on the curve. From the curve read the potencies corresponding to these corrected values of zone sizes.

(j) *Turbidimetric assay.* In lieu of the plate assay method described in paragraph (h) of this section the sample may be assayed for potency by the following turbidimetric method:

(1) *Test culture and media.* Employ the agar described in paragraph (b) of this section (adjusted to a final pH 7.0) for maintaining the test organism, which is Klebsiella pneumoniae (P. C. I. 602) noncapsulated. Transfer stock cultures every 2 weeks for test purposes. Transfer the organism to fresh agar slants and incubate overnight at 37° C. Suspend the growth from two or three of these slants in sterile distilled water and add approximately 5 milliliters of culture suspension to each of two Roux bottles containing the agar described in paragraph (b) of this section. Incubate the bottles overnight at 37° C., harvest the growth, and suspend in sufficient sterile distilled water to give a light transmission reading of 65 percent, using a filter at 6,500 Angstrom units in a photoelectric colorimeter. Keep the resulting suspension of organisms in the refrigerator and use for a period not to exceed 2 weeks. Prepare a daily inoculum by adding 6.0 milliliters of this suspension to each 100 milliliters of the nutrient broth prepared as directed in § 141a.1 (b) (3) of this chapter, cooled to a temperature of approximately 15° C.

(2) *Working standard solutions.* Add the amounts tabulated below of a 1,000 micrograms per milliliter solution prepared from the stock solution described in paragraph (c) of this section to 100-milliliter volumetric flasks containing sterile distilled water and bring to volume to give the working stock solutions tabulated below. These 9 flasks are well stoppered and maintained at approximately 15° C. for 1 month. Prepare the final dilutions daily by adding 4.2 milliliters of each of these 9 working stock solutions to 9.6 milliliters of sterile distilled water. Add 1.0 milliliter of each final dilution to each of six tubes having an outside dimension of 16 millimeters× 125 millimeters (total 54 tubes). Add 9.0 milliliters of inoculated broth described in subparagraph (1) of this paragraph to each tube and place immediately in a 37° C. water bath for 3 to 4 hours. The final concentration of strep-

tomycin per milliliter of broth is also included in the table below.

Amount of standard solution (1,000 micrograms/ml.)	Working concentration/ml. (also percent concentration)	Final concentration (micrograms/ml.) after addition of distilled water and broth
Ml.	*Micrograms*	*Micrograms*
6.0	60	1.8
7.0	70	2.1
8.0	80	2.4
9.0	90	2.7
10.0	100	3.0
11.0	110	3.3
12.0	120	3.6
13.0	130	3.9
14.0	140	4.2

(3) *Preparation of sample.* Dilute the sample under test with sterile distilled water to contain 100 micrograms per milliliter (estimated). To 4.2 milliliters of the sample add 9.6 milliliters sterile distilled water. Add 1.0 milliliter of this dilution to each of six 16 millimeter by 125 millimeter tubes (outside dimension). Add 9.0 milliliters of the inoculated broth described in subparagraph (1) of this paragraph to each tube and place immediately in a 37° C. water bath for 3 to 4 hours. A control tube containing 1.0 milliliter of distilled water and 9.0 milliliters of the inoculated broth is similarly incubated. After incubation, add 0.5 milliliter of formalin diluted 1:3 to each tube and read the light transmission in a photo-electric colorimeter, using a broad band filter having a wave length of 5,300 angstrom units.

(4) *Estimation of potency.* Average the light transmission readings for each concentration of the standard. Plot these values on cross section paper, employing average light transmission readings as the ordinate, and streptomycin concentration per milliliter of broth as the abscissa. Prepare the standard curve by connecting successive points with a straightedge. Since the final concentration of streptomycin per milliliter of broth is equivalent to the concentration per milliliter of the working stock solution (see table in subparagraph (2) of this paragraph) the latter concentrations for each concentration level of the standard may be expressed as percent and substituted on the abscissa of the standard curve. If this is done the percent potency of the sample under test may be read directly from the standard curve.

(k) *Potency.* The potency of streptomycin is satisfactory, when assayed by the methods described in this section, if the immediate containers contain 90 percent of the number of grams they are represented to contain.

§ 141b.102 *Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; sterility.* Use the entire contents of single-dose containers or the equivalent of approximately 0.5 gram (activity) from each multiple-dose container, and proceed as directed in § 141a.2 of this chapter, except that neither penicillinase nor the control tube is used in the test for bacteria.

§ 141b.103 *Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; toxicity.* Proceed as directed in § 141a.4 of this chapter, using as a test dose 0.5 milliliter of a solution containing 2 mg./ml.

§ 141b.104 *Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; pyrogens.* Proceed as directed in § 141a.3 of this chapter, using as a test dose 1.0 milliliter per kilogram of a solution containing 10 mg./ml.

§ 141b.105 *Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride; histamine.* Use a healthy adult cat as the test animal. Determine weight and place under general anesthesia by employing sufficient (150 mg./kg.) sodium phenobarbital administered intraperitoneally. Surgically expose the right carotid separating it completely from all surrounding structures, including the vagus nerve, by blunt dissection and cannulate. Surgically expose the femoral vein. Start the recording kymograph and inspect the tracings for amplitude of excursion and relative stability of pressure. Determine the sensitivity of the animal by injecting into the femoral vein standard solutions of histamine made to contain the equivalent of 1.0 microgram of histamine base per milliliter. Make injections at not less than 5-minute intervals using doses of 0.05, 0.1, and 0.15 microgram of histamine base per kilogram. Repeat these injections, disregarding the first series of readings, until the drop given by equivalent doses of histamine is relatively uniform. The fall in blood pressure given by 0.1 mcg./kg. of histamine base (not less than 20 millimeters of mercury) is subsequently employed as the standard in testing samples. The histamine standard is supplied on request. Inject 3 mg./kg. of the sample of streptomycin per milliliter maintaining the five-minute injection schedule. If a significant drop is encountered the dose is repeated after the animal has been retested with the standard histamine. The animal may be used as long as it remains reasonably stable and responsive to histamine. The product is satisfactory if the fall in blood pressure obtained with 3 milligrams of streptomycin per kilogram of body weight is no greater than the fall obtained with 0.1 microgram of histamine base per kilogram of body weight. (Dogs may be substituted for cats in this test provided the ratio of the doses of streptomycin and histamine employed is the same.)

§ 141b.106 *Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride*—(a) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

(b) *pH.* Proceed as directed in § 141a.5 (b) of this chapter, using a solution with a concentration of 0.2 gm./ml.

§ 141b.107 *Streptomycin ointment, dihydrostreptomycin ointment; potency*—(a) *Streptomycin content.* Proceed as directed in § 141b.101 except paragraphs (j) and (k) thereof, and in lieu of the directions in § 141b.101 (e), prepare the sample as follows:

Accurately weigh the tube and contents and squeeze approximately 1.0 gram into a blending jar containing 50 milliliters of 0.10 *M* potassium phosphate buffer (pH 7.8 to 8.0). Reweigh the tube to obtain weight of ointment used in the test. Using a high-speed blender, blend the mixture for 3 minutes. Dilute an aliquot of the mixture to contain 100 micrograms of streptomycin base (estimated) per milliliter. Transfer 1.0 milliliter of this solution to a 100-milliliter flask and make up to volume with 0.10 *M* potassium phosphate buffer (pH 7.8 to 8.0). Use this last dilution in the assay for potency. The potency of streptomycin ointment is satisfactory if it contains not less than 85 percent of the number of micrograms of streptomycin base per gram it is represented to contain.

(b) *Dihydrostreptomycin content.* Proceed as directed in paragraph (a) of this section, using the dihydrostreptomycin working standard as a standard of comparison. Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of micrograms of dihydrostreptomycin base per gram it is represented to contain.

§ 141b.108 *Dihydrostreptomycin sulfate, crystalline dihydrostreptomycin sulfate, dihydrostreptomycin hydrochloride*—(a) *Potency.* Using the dihydrostreptomycin working standard as a standard of comparison, proceed as directed in § 141b.101 (j) and (k).

(b) *Content of streptomycin sulfate or streptomycin hydrochloride*—(1) *Reagents.* (i) 10 percent ferric chloride stock solution. Dissolve 5 grams of $FeCl_3 \cdot 6H_2O$ in 50 milliliters 0.1 *N* HCl.

(ii) 0.25 percent ferric chloride solution—Dilute 2.5 milliliters of 10 percent ferric chloride in 0.1 *N* HCl to 100 milliliters with 0.01 *N* HCl. Prepare the solution fresh daily.

(2) *Standard curve.* Prepare a stock aqueous solution of the Food and Drug Administration working standard containing 1.0 milligram of streptomycin base per milliliter. Store this standard solution in the refrigerator and use for no longer than 2 weeks. Transfer 1.0, 2.0, 3.0, 4.0, and 5.0 milliliters of this standard solution and 10 milliliters of distilled water to each of six 25-milliliter volumetric flasks. Add 9.0, 8.0, 7.0, and 6.0 milliliters of distilled water to the first four tubes, respectively, to give each a total volume of 10 milliliters. To each add 2.0 milliliters of 1 *N* NaOH and then heat the flasks in a boiling water bath for 10 minutes. Cool the flasks in ice water for 3 minutes and acidify the solutions with 2.0 milliliters of 1.2 *N* HCl. To each flask add 5.0 milliliters of 0.25 percent ferric chloride reagent, make to volume with distilled water, and mix thoroughly. Transfer the colored solutions to 2.0-centimeter absorption cells and measure the percent light transmission at 550 mμ in a suitable photoelectric colorimeter. Set the colorimeter at 100 percent light transmission for the zero concentration

and then obtain the percent light transmission of the sample. Prepare a standard curve on semilog paper, plotting the percent light transmission on the logarithmic ordinate scale and the concentration of streptomycin base on the abscissa.

(3) *Procedure.* Dilute the contents of a 1-gram vial to 50 milliliters with distilled water (dilute vials containing larger quantities to make solutions having the same concentration). Transfer a 10-milliliter aliquot of this solution to a 25-milliliter volumetric flask, add 2.0 milliliters of 1 *N* NaOH and heat in a boiling water bath for 10 minutes. Cool in ice water for 3 minutes and acidify the solution with 2.0 milliliters of 1.2 *N* HCl. Add 5.0 milliliters of 0.25 percent ferric chloride reagent. Make to volume with distilled water. Transfer the colored solution to a 2.0-centimeter absorption cell and measure the percent light transmission at 550 mμ in a suitable photoelectric colorimeter. Set the colorimeter at 100 percent light transmission for the zero concentration and then obtain the percent light transmission of the sample. The concentration of streptomycin obtained directly from the standard curve corresponding to the percent light transmission of the sample, times 500, divided by the total milligrams per vial obtained by biological assay, equals the percent of streptomycin.

(c) *Sterility.* Proceed as directed in § 141b.102.

(d) *Toxicity, pyrogens, histamine, moisture, pH, crystallinity.* Proceed as directed in §§ 141b.103, 141b.104, 141b.105, 141b.106, and 141a.5 (c) of this chapter.

§ 141b.109 *Streptomycin tablets, dihydrostreptomycin tablets*—(a) *Potency*—(1) *Streptomycin content.* Using 12 tablets, proceed as directed in § 141b.101, except paragraphs (j) and (k) of that section, and use 0.10 *M* potassium phosphate buffer (pH 7.8–8.0) for dissolving the sample in lieu of sterile distilled water as directed in § 141b.101 (e). The average potency of streptomycin tablets is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(2) *Dihydrostreptomycin content.* Proceed as directed in subparagraph (1) of this paragraph, using the dihydrostreptomycin working standard as a standard of comparison. The average potency of dihydrostreptomycin tablets is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

§ 141b.110 *Streptomycin for topical use*—(a) *Potency.* Proceed as directed in § 141b.101, except paragraph (k) thereof. The potency of streptomycin for topical use is satisfactory if the immediate containers are represented to contain:

(1) Less than 500 milligrams and contain 85% or more of the number of milligrams so represented;

(2) More than 500 milligrams and contain 90% or more of the number of milligrams so represented.

(b) *Sterility, toxicity, pyrogens, histamine, moisture, pH.* Proceed as directed in §§ 141b.102 to 141b.106.

§ 141b.111 *Streptomycin sulfate solution, dihydrostreptomycin sulfate solution, crystalline dihydrostreptomycin sulfate solution.* (a) If it is streptomycin sulfate solution, proceed as directed in §§ 141b.101, 141b.102, 141b.104, 141b.105, and 141b.106 (b), and for the toxicity test proceed as directed in § 141a.4 of this chapter, using as a test dose 0.5 milliliter of a solution containing 1.5 milligrams per milliliter.

(b) If it is dihydrostreptomycin sulfate solution or crystalline dihydrostreptomycin sulfate solution, proceed as directed in § 141b.108, except in lieu of the directions in § 141b.108 (b) determine the streptomycin content as follows:

(1) *Preparation of standard.* Prepare a standard aqueous solution of the Food and Drug Administration streptomycin working standard containing 0.25 milligram of streptomycin base per milliliter. Transfer 1.0, 1.5, and 2.0 milliliter aliquots to test tubes (approximately 16 millimeters×150 millimeters). Add 1.0, 0.5, and 0 milliliter of distilled water to give a 2.0-milliliter volume.

(2) *Preparation of sample.* Dilute 1.0 milliliter of the dihydrostreptomycin sulfate solution to be tested (containing 250 to 500 milligrams of dihydrostreptomycin) to 25.0 milliliters in a volumetric flask. Transfer 2.0 milliliters to a test tube.

(3) *Blank.* Use 2.0 milliliters of distilled water.

(4) *Procedure.* To each tube containing 2.0 milliliters, add, in turn, 8.0 milliliters of 0.1 *N* NaOH (freshly prepared from 1 *N* NaOH), mix thoroughly, and immediately determine the optical density at 325 mμ in a suitable spectrophotometer. Set the spectrophotometer at 100-percent light transmission for the blank similarly treated. Return the solution to the test tube, heat in a boiling water bath for 10 minutes, cool in an ice bath for 3 minutes, and allow to come to room temperature. Determine the optical density at 325 mμ. The difference in reading before and after heating is the optical density of the aliquot. Prepare a standard curve. The concentration of streptomycin in the sample solution obtained directly from the standard curve times 1,250, divided by the number of milligrams of dihydrostreptomycin in the original dihydrostreptomycin solution; equals the percent of streptomycin.

§ 141b.112 *Streptomycin-polymyxin-bacitracin tablets* — (a) *Tablets* — (1) *Potency*—(i) *Streptomycin content.* Using 12 tablets, proceed as directed in § 141b.109 (a) (1). Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(ii) *Polymyxin content.* Using 12 additional tablets, proceed as directed in paragraph (b) of this section. Its content of polymyxin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(iii) *Bacitracin content.* Using an aliquot of the solution prepared under subdivision (ii) of this subparagraph, proceed as directed in § 141e.403 (a) of this chapter, except the last sentence of that paragraph and except that sufficient semi-carbazide 0.5 percent solution (pH 6.5–7.0) is added to inactivate (1 hour at room temperature) the streptomycin contained in the solution. Its content of bacitracin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

(b) *Polymyxin used in making the tablets*—(1) *Potency*—(i) *Cylinders (cups).* Use cylinders described under § 141a.1 (a) of this chapter.

(ii) *Culture medium.* Using ingredients that conform to the standards prescribed, if any, by the U. S. P. or N. F., make nutrient agar for the seed and base layers:

(*a*) *Base layer.*

Pancreatic digest of casein	17.0 gm.
Papaic digest of soybean	3.0 gm.
Sodium chloride	5.0 gm.
Dipotassium phosphate	2.5 gm.
Dextrose	2.5 gm.
Agar	20.0 gm.
Distilled water, q. s.	1,000.0 ml.
Final pH	7.3.

(*b*) *Seed layer.* For seed layer make the following changes in the medium described in (*a*) of this subdivision.

Agar	12.0 gm.
Tween 80 (add Tween 80 after boiling)	10.0 gm.
Final pH	7.3.

In lieu of preparing the medium from the individual ingredients as specified, it may be prepared from a dehydrated mixture which, when reconstituted with distilled water, has the same composition as such medium. Minor modifications of the specified individual ingredients are permissible if the resulting medium possesses growth-promoting properties at least equal to the medium described.

(iii) *Working standard.* Weigh out a sufficient quantity of the working standard (obtained from the Food and Drug Administration) and make a 10,000 units per milliliter stock solution by diluting with 1-percent phosphate buffer, pH 6.0. This solution may be used for 2 weeks if kept in the refrigerator.

(iv) *Standard curve.* Prepare daily a standard curve as directed in § 141b.101 (d) with the following exceptions: Using a solution of the polymyxin working standard in 1-percent phosphate buffer, pH 6.0, prepare volumetrically the following concentrations: 60, 70, 80, 90, 100, 110, 120, 130, 140, and 150 units per milliliter in 1-percent phosphate buffer, pH 6.0. The 100 units per milliliter is used as the reference point.

(v) *Preparation of test organism.* The test organism is Brucella bronchiseptica (American Type Culture Collection 4617) which is maintained on agar described under subdivision (ii) (*a*) of this subparagraph. Inoculate a Roux bottle containing this agar, subdivision (ii) (*a*), from a stock slant and incubate 24 hours at 32° C.–35° C. Wash the growth into sterile distilled water and standardize the resulting organism suspension to 50-percent light transmission using a filter having a wave length of 6,500 A. Run test plates, and use in the assay the amount of inoculum per 100 milliliters of seed agar which gives (ca) 15.0-millimeter zones of inhibition against the test organism with the 100 units per milliliter solution of polymyxin. Make a new suspension every two weeks.

(vi) *Preparation of plates.* Using the agar described in subdivision (ii) of this subparagraph, prepare the plates as described in § 141b.101 (g), except allow the agar for the secondary layer to cool to 48° C.–50° C. before adding the inoculum. It is not necessary to refrigerate the plates.

(vii) *Assay.* Dissolve volumetrically into sterile 1-percent phosphate buffer, pH 6.0, the sample to be tested to a final concentration of 100 units (estimated) per milliliter, and proceed as directed in § 141b.101 (h) and (i).

(2) *Toxicity.* Proceed as directed in § 141a.4 of this chapter, using 0.5 milliliter of a solution prepared by diluting the sample to approximately 1,200 units per milliliter with physiological salt solution.

§ 141b.113 *Streptomycin syrup, streptomycin and kaolin in gel, dihydrostreptomycin syrup, dihydrostreptomycin and kaolin in gel; potency.* Proceed as directed in § 141b.101, except paragraph (k) thereof, and except if it is dihydrostreptomycin use the dihydrostreptomycin working standard as a standard of comparison. Its potency is satisfactory if it contains not less than 85 percent of the number of milligrams of streptomycin or dihydrostreptomycin per milliliter that it is represented to contain.

§ 141b.114 *Streptomycin-bacitracin-polymyxin gauze pads*—(a) *Potency.* Proceed as directed in § 141b.112 (a) (1), except soak the sample for not less than 1 hour with frequent agitation.

(b) *Sterility.* Using individual pads proceed as directed in § 141b.102. This method will demonstrate only those organisms which are not susceptible to these concentrations of streptomycin, bacitracin, and polymyxin.

(c) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

§ 141b.115 *Streptomycin otic with antifungal agent, dihydrostreptomycin otic with antifungal agent*—(a) *Potency.* Proceed as directed in § 141b.101, except paragraph (k) thereof, and if it is dihydrostreptomycin otic with antifungal agent use the dihydrostreptomycin working standard as a standard of comparison. Its potency is satisfactory if it contains not less than 85 percent of the number of milligrams of streptomycin or dihydrostreptomycin per milliliter that it is represented to contain.

(b) *pH.* Proceed as directed in § 141a.5 (b) of this chapter, using the undiluted solution or suspension.

§ 141b.116 *Streptomycin-kaolin-pectin-aluminum hydroxide gel powder veterinary, dihydrostreptomycin-kaolin-pectin-aluminum hydroxide gel powder veterinary*—(a) *Potency*—(1) *Streptomycin content.* Using 3.0 grams of the sample, proceed as directed in § 141b.101, except paragraph (k) of that section. Its potency is satisfactory if it contains not less than 85 percent of the number of milligrams of streptomycin it is represented to contain.

(2) *Dihydrostreptomycin content.* Proceed as directed in subparagraph (1) of this paragraph, using the dihydrostreptomycin working standard as a standard of comparison. Its potency is satisfactory if it contains not less than 85 percent of the number of milligrams of dihydrostreptomycin it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

§ 141b.117 *Streptomycin for inhalation therapy, dihydrostreptomycin for inhalation therapy*—(a) *Potency*—(1) *Streptomycin content.* Proceed as directed in § 141b.101, except if it is packaged with inert gases proceed as follows: Use not less than 6 immediate containers. Place one-half the number of such containers in a suitable sharp freezing unit having a temperature not higher than −30° C. After freezing, cut open the containers and transfer the contents of each to a suitable beaker and allow gas to evaporate. After gas has evaporated, wash and dry the residue remaining in the container into the beaker with sterile distilled water, after which wash the entire contents of the beaker into a 500-milliliter volumetric flask and make to mark with sterile distilled water. Use an appropriate aliquot of each of these solutions and proceed as directed in § 141b.101 to determine the average total quantity of streptomycin in each container. Expel the drug from each of the remaining containers as directed in its labeling. After all gas (with drug) has been expelled, cut open the containers and place each in a large beaker containing 500 milliliters of sterile distilled water. Let stand for not less than 15 minutes, with frequent agitation. Remove an aliquot and proceed as directed in § 141b.101 to determine the quantity of streptomycin that remains in each container. The quantity of streptomycin expelled is determined by subtracting the average amount of the residue found from the average total amount contained in the containers. Its potency is satisfactory if it contains not less than 90 percent, or 85 percent if it is packaged with inert gases, of the number of milligrams of streptomycin that it is represented to contain.

(2) *Dihydrostreptomycin content.* Proceed as directed in subparagraph (1) of this paragraph, except use the dihydrostreptomycin working standard as a standard of comparison. Its potency is satisfactory if it contains not less than 90 percent, or 85 percent if it is packaged with inert gases, of the number of milligrams of dihydrostreptomycin that it is represented to contain.

(b) *Unless it is packaged with inert gases, toxicity, histamine, moisture, pH, streptomycin content (if it is dihydrostreptomycin), crystallinity (if it is crystalline dihydrostreptomycin).* Proceed as directed in §§ 141b.103, 141b.105, 141b.106, 141b.108 (b), and 141a.5 (c) of this chapter.

(c) *If it is packaged with inert gases, moisture.* Proceed as directed in § 141a.7 (c) of this chapter, but in lieu of the directions for preparing the sample in § 141a.7 (c) (3) of this chapter prepare the sample and calculate as follows: Freeze the container as described in paragraph (a) of this section. After freezing, open the container and remove a representative 10-milliliter aliquot. Place this sample in a dry titrating vessel, immediately add an excess of Karl Fischer reagent, and back-titrate with water-methanol solution until the end-point is reached.

$$\text{Percent moisture} = \frac{(v_1 - V_2 f)\,Xe}{100}$$

§ 141b.118 *Dihydrostreptomycin-streptomycin sulfates*—(a) *Potency.* Proceed as directed in § 141b.108 (a). Its total potency is satisfactory if it contains not less than 90 percent of the combined number of milligrams of dihydrostreptomycin and streptomycin that it is represented to contain.

(b) *Content of streptomycin sulfate.* Proceed as directed in § 141b.108 (b), making appropriate dilutions so that the aliquot used for the colorimetric measurement contains 5.0 milligrams of streptomycin (estimated) and modify the calculations in accordance with the dilutions made. Its content of streptomycin is satisfactory if it contains not less than 45 percent and not more than 55 percent of the total potency as determined under paragraph (a) of this section.

(c) *Sterility, toxicity, pyrogens, histamine, moisture, pH.* Using the total potency of the sample for preparing dilutions and weighings, proceed as directed in §§ 141b.102, 141b.103, 141b.104, 141b.105, and 141b.106.

§ 141b.119 *Streptomycin sulfate oral veterinary*—(a) *Potency.* Proceed as directed in § 141b.101.

(b) *Toxicity.* Proceed as directed in § 141b.103.

(c) *Moisture.* Using a 1-gram sample, proceed as directed in § 141a.5 (a) of this chapter.

(d) *pH.* Proceed as directed in § 141b.106 (b).

§ 141b.120 *Streptomycin sulfate powder oral veterinary; streptomycin sulfate granules oral veterinary*—(a) *Potency.* Proceed as directed in § 141b.101. Its content of streptomycin is satisfactory if it contains not less than 90 percent of the number of milligrams of streptomycin per gram it is represented to contain.

(b) *Moisture.* Using a 1-gram sample, proceed as directed in § 141a.5 (a) of this chapter.

§ 141b.121 *Streptomycylidene isonicotinyl hydrazine sulfate*—(a) *Potency*—(1) *Streptomycin content.* Dilute the sample with hydrochloric acid solution pH 1.5 to 1,000 micrograms per milliliter (estimated streptomycin activity). Heat at 50° C. for 30 minutes, cool rapidly and proceed as directed in § 141b.101. The streptomycin potency of streptomycylidene isonicotinyl hydrazine sulfate is satisfactory if the immediate containers contain 90 percent of the streptomycin activity they are represented to contain.

(2) *Isonicotinic acid hydrazide content*—(i) *Reagents.* (*a*) 0.1 *N* $KBrO_3$-KBr solution: Dissolve 3 grams of $KBrO_3$

and 15 grams of KBr in sufficient water to make 1,000 milliliters.

(*b*) Concentrated hydrochloric acid.

(*c*) 20-percent potassium iodide solution.

(*d*) 0.05 *N* $Na_2S_2O_3$ (accurately standardized against KIO_3).

(ii) *Preparation of sample.* Place an accurately weighed sample of approximately 250 milligrams or an aliquot of a solution containing 250 milligrams of streptomycylidene isonicotinyl hydrazine sulfate into a 250-milliliter iodine flask. Add sufficient water to give a volume of 25 milliliters.

(iii) *Blank.* Add 25 milliliters of distilled water in a 250-milliliter iodine flask.

(iv) *Procedure.* To each iodine flask containing the sample and blank, add 25 milliliters of 0.1 *N* $KBrO_3$-KBr solution and 5 milliliters of concentrated HCl. Stopper the flasks, and place distilled water in the wells around the stopper. Allow the flasks to stand for 15 minutes at room temperature, and then add 5 milliliters of 20-percent potassium iodide solution to each flask. Titrate the liberated iodine with 0.05 *N* $Na_2S_2O_3$, using starch as an indicator.

(v) *Calculations.*

$$\text{Percent isonicotinic acid hydrazide}=\frac{(B-S)\times N\times 3429}{W}$$

where:

B= milliliters of $Na_2S_2O_3$ required for the blank.

S= milliliters of $Na_2S_2O_3$ required for the sample.

N= normality of the $Na_2S_2O_3$

W= milligrams of sample.

(b) *Extinction coefficient.* Accurately weigh approximately 100 milligrams of the sample, dissolve in distilled water, and make to 100 milliliters. Dilute a 5-milliliter aliquot of this solution to 100 milliliters, allow to stand at room temperature for 15 minutes, and, using a suitable spectrophotometer, determine the optical density of the solution in a 1-centimeter cell at 260 millimicrons compared with distilled water as a blank.

$$E\frac{1\text{ percent}}{1\text{ centimeter}}=\frac{(\text{optical density})\ (20{,}000)}{\text{weight of sample in milligrams}}$$

(c) *Toxicity.* Proceed as directed under § 141a.4 of this chapter, using as a test dose 0.5 milliliter of a solution containing 1,000 micrograms of streptomycin activity per milliliter.

(d) *Sterility.* Proceed as directed under § 141a.2 of this chapter, using the equivalent of approximately 0.5 gram streptomycin activity, except that neither penicillinase nor the control tube is used in the test for bacteria.

(e) *Pyrogens, histamine, moisture, pH, and crystallinity.* Proceed as directed under §§ 141b.104, 141b.105, 141b.106, and 141a.5 (c) of this chapter.

§ 141b.122 *Dihydrostreptomycin-streptomycin sulfates solution*—(a) *Combined potency of dihydrostreptomycin and streptomycin; content of streptomycin.* Proceed as directed in § 141b.118 (a) and (b).

(b) *Sterility, toxicity, pyrogens, histamine.* Proceed as directed in §§ 141b.102, 141b.103, 141b.104, and 141b.105.

(c) *pH.* Using the undiluted solution, proceed as directed in § 141a.5 (b) of this chapter.

§ 141b.123 *Streptomycin - penicillin-sulfonamide with kaolin and pectin, dihydrostreptomycin-penicillin-sulfonamide with kaolin and pectin*—(a) *Potency*—(1) *Streptomycin content.* Proceed as directed in § 141b.101. Its potency is satisfactory if it contains not less than 90 percent of the number of milligrams of streptomycin it is represented to contain.

(2) *Dihydrostreptomycin content.* Proceed as directed in subparagraph (1) of this paragraph, using the dihydrostreptomycin working standard as a standard of comparison. Its potency is satisfactory if it contains not less than 90 percent of the number of milligrams of dihydrostreptomycin it is represented to contain.

(3) *Penicillin content.* Proceed as directed in § 141a.1 of this chapter. Its potency is satisfactory if it contains not less than 90 percent of the number of units of penicillin it is represented to contain.

(b) *Moisture content.* Proceed as directed in § 141a.5 (a) of this chapter.

(c) *pH.* Prepare the suspension as directed in the labeling of the drug and proceed as directed in § 141a.5 (b) of this chapter.

§ 141b.124 *Streptomycin-hydrochloride solution oral veterinary; streptomycin sulfate solution oral veterinary*—(a) *Potency.* Proceed as directed in § 141b.101. Its potency is satisfactory if it contains not less than 90 percent of the number of milligrams of streptomycin per milliliter that it is represented to contain.

(b) *Toxicity.* Proceed as directed in § 141b.103.

(c) *pH.* Proceed as directed in § 141b.106 (b).

§ 141b.125 *Dihydrostreptomycin-streptomycin sulfates with isonicotinic acid hydrazide*—(a) *Total potency*—(1) *Preparation of sample*—(i) *Reagents*—(*a*) *Benzaldehyde.* Boiling point 75–76° C./16 millimeters;

(*b*) *Acetone.* Reagent grade.

(ii) *Apparatus.* An extraction funnel is prepared by fusing a ground-glass stopper to the top of a medium porosity sintered-glass filter funnel (30-millimeter diameter).

(iii) *Procedure.* The entire sample is quantitatively transferred to the funnel as follows: Pour the dry sample into the funnel. Wash any material remaining in the bottle with three 5.0-milliliter portions of benzaldehyde, placing the washings into the funnel. Stopper the funnel and shake occasionally for 3 minutes. Filter off the benzaldehyde by vacuum. Repeat the shaking with two more 15-milliliter portions of benzaldehyde, discarding all benzaldehyde filtrates. Wash the residue in the funnel with about 10 milliliters of acetone, discarding the acetone filtrate. Dissolve the streptomycin and dihydrostreptomycin in the funnel with about 25 milliliters of water and transfer the solution to a 500-milliliter volumetric flask. Wash the funnel with water and transfer the washings to the volumetric flask. Finally, wash the funnel with water by filtering the water by vacuum and add the filtrate to the volumetric flask. Dilute the sample to 500 milliliters with distilled water, then proceed as directed in § 141b.101 (j), using the dihydrostreptomycin working standard as the standard of comparison. The total potency is satisfactory if it contains not less than 90 percent of the combined number of milligrams of dihydrostreptomycin and streptomycin that it is represented to contain.

(b) *Content of streptomycin sulfate.* Using an aliquot of the solution prepared as directed in paragraph (a) of this section, proceed as directed in § 141b.108 (b), making appropriate dilutions so that the aliquot ultimately used for the colorimetric measurement contains 5.0 milligrams of streptomycin (estimated), and modify the calculations in accordance with the dilutions made. Its content of streptomycin is satisfactory if it contains not less than 45 percent and not more than 55 percent of the total potency as determined under paragraph (a) of this section.

(c) *Isonicotinic acid hydrazide content.* Proceed as directed under § 141b.121 (a) (2).

(d) *Sterility, pyrogens, histamine, moisture, pH.* Using the total potency of the sample for preparing dilutions and weighings, proceed as directed in §§ 141b.102, 141b.104, 141b.105, and 141b.106.

(e) *Toxicity.* Proceed as directed under § 141a.4 of this chapter, using as a test dose 0.5 milliliter of a solution containing 1,000 micrograms of total activity per milliliter.

§ 141b.126 *Streptomycin-erythromycin ointment*—(a) *Ointment*—(1) *Potency*—(i) *Streptomycin content.* Proceed as directed in § 141b.101 (a) through (i), except prepare the sample as follows: Place a representative quantity of the ointment (usually an entire container) in a blending jar containing approximately 225 milliliters of chloroform. Using a high-speed blender, blend the mixture for 3 minutes. Transfer the blended material to a large Buchner funnel (at least 10 centimeters in diameter) fitted with a highly retentive filter paper and attached to a vacuum line. Apply vacuum long enough to insure removal of chloroform from the filter cake. Place the filter cake and the paper in a blending jar containing 250 milliliters of 0.1 *M* phosphate buffer, pH 8.0, and blend for 10 minutes. Filter the blended material through a fast, porous, filter paper. Dilute the filtrate to obtain a solution for assay containing 1.0 microgram per milliliter. Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram that it is represented to contain.

(ii) *Erythromycin content*—(*a*) *cylinders* (*cups*). Use cylinders described under § 141a.1 (a) of this chapter.

(*b*) *Culture media*. Prepare the culture media for the base and seed layers and for carrying the test organism as directed in § 141a.1 (b) (1) of this chapter, except for the base and seed layers adjust the media to pH 8.0 after sterilization. Make the nutrient broth for preparing an inoculum of the test organism as directed in § 141a.1 (b) (3) of this chapter.

(*c*) *Working standard*. Keep the working standard at refrigeration in tightly stoppered vials, which in turn are kept in larger stoppered vials containing a suitable desiccant. Dry 30 to 50 milligrams of the standard as described in § 141a.5 (a) of this chapter. Dissolve the weight of dry working standard in sufficient methyl alcohol to give a concentration of 10,000 micrograms per milliliter. Further dilute with 0.1 *M* potassium phosphate buffer, pH 7.8 to 8.0, to give a stock solution of 1,000 micrograms per milliliter. This stock solution may be kept under refrigeration for 1 week.

(*d*) *Standard curve*. Using the working-standard stock solution, prepare a standard curve as directed in § 141b.101 (d).

(*e*) *Preparation of spore suspension*. The test organism is Sarcina lutea (P. C. I. 1001). Maintain the test organism on slants of nutrient agar described in (*b*) of this subdivision and transfer to a fresh agar slant once a week. Prepare a suspension of the test organism as follows: Streak an agar slant heavily with the test organism. Wash the growth off in about 3 milliliters of nutrient broth described in (*b*) of this subdivision. Use the suspension so obtained to inoculate the surface of a Roux bottle containing 300 milliliters of the nutrient agar. Spread the suspension over the entire surface with the aid of sterile glass beads. Incubate for 24 hours at 26° C. Wash the growth from the agar surface with 20 milliliters of nutrient broth described in (*b*) of this subdivision. If an aliquot of this bulk suspension, when diluted with nutrient broth 1:10, gives a 10-percent light transmission in a suitable photoelectric colorimeter equipped with a filter having a wave length of 6,500 Angstrom units, it is satisfactory for use. It may be necessary to adjust the bulk suspension by dilution, so that an aliquot of the adjusted suspension diluted 1:10 gives 10-percent light transmission. (The adjusted bulk suspension only, and not the 1:10 dilution of it, is used in preparing the seed layer.) The bulk suspension may be used in the test for 2 weeks. Add 0.3 milliliter of the adjusted bulk suspension to 100 milliliters of agar described in (*b*) of this subdivision, which has been melted and cooled to 48° C.

(*f*) *Preparation of plates*. Add 21 milliliters of the agar prepared in (*b*) of this subdivision to each Petri dish (20 mm. x 100 mm.). Distribute the agar evenly in the plates and allow it to harden. Use the plates the same day they are prepared. Add 4.0 milliliters of the inoculum prepared under (*e*) of this subdivision to each plate, tilting the plates back and forth to spread the inoculated agar evenly over the surface.

(*g*) *Assay*. Place a representative quantity of the ointment (usually an entire container) in a blending jar containing approximately 225 milliliters of polyethylene glycol. Using a high-speed blender, blend the mixture for 10 minutes and filter through a Buchner filter. Dilute the filtrate to 1.0 microgram per milliliter (estimated) in 0.1 *N* potassium phosphate buffer, pH 8.0, and proceed as directed in § 141b.101 (h) and (i), except that the incubation temperature is 32° C. to 35° C.

Its content of erythromycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram that it is represented to contain.

(iii) *Moisture*. Proceed as directed in § 141a.7 (c) of this chapter.

(b) *Erythromycin used in making the ointment*—(1) *Moisture*. Proceed as directed in § 141a.26 (e) of this chapter. Use the value obtained to calculate the weighed samples used in this paragraph.

(2) *Potency*. Proceed as directed in paragraph (a) (1) (ii) of this section, except in the preparation of the solution of the sample dissolve 40 milligrams (as the anhydrous compound) in a small amount of methyl alcohol and then further dilute in 0.10 *M* potassium phosphate buffer, pH 8.0, to make a solution containing 1.0 microgram per milliliter (estimated).

(3) *Toxicity*. Proceed as directed in § 141d.305 (b) of this chapter, except administer orally to each mouse 1.0 milliliter of a suspension of the drug containing 30 milligrams per milliliter.

(4) *pH*. Using a saturated aqueous solution (100 milligrams per milliliter), proceed as directed in § 141a.5 (b) of this chapter.

(5) *Color-identity test*. Dissolve about 3 milligrams of the sample in 2 milliliters of acetone and add an equal volume of concentrated hydrochloric acid. A rapid color development takes place beginning with orange, changing to red, and finally resulting in a deep purple. Shake with 2 milliliters of chloroform. A portion of the purple color extracts into the chloroform layer.

§ 141b.127 *Streptomycin-chlortetracycline-chloramphenicol-bacitracin dental cement; dihydrostreptomycin-chlortetracycline-chloramphenicol-bacitracin dental cement*—(a) *Potency*—(1) *Streptomycin or dihydrostreptomycin content*—(i) *Reagents*. (*a*) Sodium nitroprusside solution, 10 percent (w/v).

(*b*) Potassium ferricyanide solution, 10 percent (w/v).

(*c*) Sodium hydroxide solution, 10 percent (w/v).

(*d*) Oxidized nitroprusside solution.

Mix equal volumes of the 10-percent sodium nitroprusside, 10-percent potassium ferricyanide, and 10-percent sodium hydroxide solutions in the order named. A deep-red color is formed which changes to a yellow green after standing at room temperature for approximately 15 minutes. Dilute 1.0 milliliter of this yellow-green solution with water to 100 milliliters and shake. This is the oxidized nitroprusside solution to be used in the test. It should be prepared fresh daily. Each of the 10-percent solutions described is stable for at least 2 months when stored in amber bottles.

(*e*) 0.3 percent piperidine in acetone.

(*f*) Aectone.

(ii) *Preparation of standard*. Prepare aqueous solutions of the working standards of streptomycin or dihydrostreptomycin containing 0.2 milligram per milliliter. Transfer 1.0, 2.0, 3.0, 4.0, 5.0, 6.0, and 7.0 milliliter portions to small flasks. Add sufficient water to give each a 10-milliliter volume.

(iii) *Preparation of sample*. Place an accurately weighed portion of approximately 700 milligrams of the dental cement in a sintered-glass filter funnel and wash with three successive 5-milliliter portions of 0.3-percent piperidine in acetone. Remove any residual piperidine with two 5-milliliter portions of acetone and suck dry with vacuum. To the residue on the filter add 10 milliliters of distilled water and 10 milliliters of the oxidized nitroprusside solution. Shake, and after 6 minutes filter and read the color as directed below.

(iv) *Blank*. Use 10 milliliters of distilled water.

(v) *Procedure*. To each flask containing 10 milliliters of the standard and blank add 10 milliliters of the oxidized nitroprusside solution and allow the color to develop at room temperature for 6 minutes. Determine the optical density of each of the standard solutions and the sample at 490 millimicrons, using a suitable spectrophotometer. The blank is used to set the instrument to zero optical density. The orange-red color produced is stable for 30 minutes. Prepare a standard curve on coordinate graph paper, plotting the optical density on the ordinate scale and the concentration of streptomycin or dihydrostreptomycin base on the abscissa. For the sample, the optical density found is used to obtain the concentration of streptomycin or dihydrostreptomycin directly from the standard curve. To obtain the potency of the sample, multiply the concentration found by the appropriate factors in accordance with the dilutions made. Its content of streptomycin or dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(2) *Chlortetracycline content*—(i) *Reagents*. Mix 8 volumes of 20-percent (w/v) K_2HPO_4 with 1 volume of 20-percent (w/v) KH_2PO_4.

(ii) *Apparatus*. (*a*) A Coleman electronic photofluorometer (Model 12) or a similar instrument, equipped with filter b–1 for incident light and filter b–2 for emitted fluorescence.

(*b*) Matched 18 x 150-millimeter Pyrex test tubes.

(iii) *Preparation of standards*. (*a*) Prepare the fluorometric standard by dissolving 20 milligrams of U. S. P. quinine sulfate in 1 liter of 0.1 *N* H_2SO_4. Dilute 5 milliliters of this stock standard to 200 milliliters with 0.1 *N* H_2SO_4. Store these standards in the dark.

(*b*) Prepare solutions of the chlortetracycline hydrochloride working standard to contain 5, 10, and 20 micrograms per 10 milliliters.

(iv) *Procedure.* Using the diluted quinine standard, set the fluorometric reading at 35.0. Make a homogenous slurry of 500 milligrams of the dental cement in 500 milliliters of water. Place a 10-milliliter portion of the slurry in one of the matched test tubes and add 2.0 milliliters of the buffer reagent. Centrifuge for 3 minutes at 3,000 r. p. m. and immediately read the blank fluorescence of this solution. Stir the solution and heat on a steam bath for 5 minutes. Cool, and wipe the inside surface of the test tube with a swab of glass wool. Centrifuge for 5 minutes at 3,000 r. p. m. and read the fluorescence within 1 hour. Subtract the initial blank fluorescence reading. Calculate the chlortetracycline content by reference to a standard curve prepared by treating the chlortetracycline standard solutions in a similar fashion. It is not necessary to centrifuge the standard solutions. Its content of chlortetracycline is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(3) *Chloramphenicol content*—(i) *Reagents.* (*a*) Ethyl acetate.

(*b*) Sodium hydrosulfite.

(*c*) 0.1 *N* NaOH.

(*d*) 5-percent $NaNO_2$.

(*e*) Concentrated HCl.

(*f*) 5-percent ammonium sulfamate.

(*g*) 0.5-percent N(1-naphthyl) ethylenediamine dihydrochloride.

(ii) *Standard.* Prepare the standard by dissolving 20 milligrams of chloramphenicol working standard in 500 milliliters of water.

(iii) *Procedure.* Place 500 milligrams of the dental cement in a 50-milliliter volumetric flask and add 25 milliliters of ethyl acetate. Heat to boiling on a steam bath. Cool and dilute to mark with ethyl acetate. Centrifuge, and place 15 milliliters of the clear solution in a 100-milliliter volumetric flask. Evaporate to dryness on a steam bath with the aid of a stream of compressed air. Dissolve the residue in a 3-milliliter portion of 0.1 *N* NaOH, add 25 milligrams of sodium hydrosulfite, and let stand at room temperature for 15 minutes. Add 0.5 milliliter of 5-percent $NaNO_2$ and 5 to 10 drops of concentrated HCl. After 2 minutes, add 1 milliliter of ammonium sulfamate. Wait 2 minutes and add 0.5 milliliter of N(1-naphthyl) ethylenediamine dihydrochloride. Make to 100 milliliters and after 2 hours read the absorbance at 558 millimicrons in a 2-centimeter cell against a reagent blank, using a suitable spectrophotometer. To 4.0, 5.0, and 6.0 milliliter portions of the standard chloramphenicol solution add 3 milliliters of 0.1 *N* NaOH and proceed as above, beginning with the addition of 25 milligrams of sodium hydrosulfite. From the readings obtained plot a standard curve and calculate the quantity of chloramphenicol in the sample from the standard curve. Its content of chloramphenicol is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(4) *Bacitracin content.* Weigh 2 grams of the dental cement and transfer to a sintered-glass funnel of medium porosity. Wash the cement six times with 5-milliliter portions of 0.3 percent piperidine in acetone solution, using an Erlenmeyer suction flask and vacuum. Wash the residue with four 10-milliliter portions of distilled water. Withdraw under vacuum, pool washings, and add sufficient water to give a bacitracin concentration of 2 units per milliliter. To a 10-milliliter portion of this solution add 2 milliliters of a buffer solution consisting of 8 parts of a 20-percent dibasic potassium phosphate solution and 1 part of a 20-percent monobasic potassium phosphate solution. Heat this solution with steam for 3½ minutes and cool immediately. Adjust to pH 6.0 with approximately 1.5 milliliters of 1 *N* HCl and add enough sterile distilled water to give a final bacitracin concentration of 1 unit per milliliter. Assay by the method prescribed in § 141a.49 of this chapter, using the dihydrostreptomycin-resistant strain of M. flavus (P. C. I. 16 R. D.). Its content of bacitracin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

§ 141b.128 *Streptomycin-sodium sulfathiazole solution veterinary; dihydrostreptomycin-sodium sulfathiazole solution veterinary*—(a) *Potency.* Proceed as directed in § 141b.101 (j), except if it contains dihydrostreptomycin use the dihydrostreptomycin working standard as a standard of comparison. Its content of streptomycin or dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(b) *Sterility, pyrogens, histamine, streptomycin content if it is dihydrostreptomycin.* Proceed as directed in §§ 141b.102, 141b.104, 141b.105, and 141b.111 (b).

(c) *Toxicity.* Proceed as directed in § 141a.4 of this chapter, using as a test dose 0.5 milliliter of a solution containing 1.5 milligrams of streptomycin or dihydrostreptomycin per milliliter.

(d) *pH.* Proceed as directed in § 141a.5 (b) of this chapter, using the undiluted drug.

§ 141b.129 *Streptomycin-polymyxin-neomycin ointment; dihydrostreptomycin-polymyxin-neomycin ointment* (a) *Potency*—(1) *Streptomycin content.* Proceed as directed in § 141b.101 (a) through (i), inclusive, except prepare the sample in one of the following ways:

(i) *Extraction.* Place a convenient sized representative quantity of the sample in a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake the sample and ether until homogenous. Add a 20-milliliter portion of 0.1 *M* potassium phosphate buffer, pH 8.0, and shake well. Remove the buffer layer and repeat the extraction with 20-milliliter portions of buffer at least three times and any additional times that may be necessary to insure complete extraction of the antibiotic. Combine the extractives and make the appropriate estimated dilutions in 0.1 *M* potassium phosphate buffer, pH 8.0.

(ii) *Blending.* Place a convenient sized representative quantity of the sample in a blending jar containing 1.0 milliliter of a 10-percent aqueous solution of polysorbate 80 and sufficient 0.1 *M* potassium phosphate buffer, pH 8.0, to give a volume of 200 milliliters. Using a high-speed blender, blend for 2 minutes and then make the appropriate estimated dilutions with buffer. Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram that it is represented to contain.

(2) *Dihydrostreptomycin content.* Proceed as directed in subparagraph (1) of this paragraph, using the dihydrostreptomycin working standard as a standard of comparison. Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram that it is represented to contain.

(3) *Polymyxin content.* Proceed as directed in § 141b.112 (b) (1) with the following exceptions:

(i) In lieu of the directions for the preparation of the sample described in subdivision (vii) of § 141b.112 (b) (1), prepare the sample as follows: Place a convenient sized representative quantity of the sample in a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake the sample and ether until homogeneous. Add 25 milliliters of 10-percent potassium phosphate buffer, pH 6.0, containing 2 grams of K_2HPO_4 and 8 grams of KH_2PO_4 in each 100 milliliters, and shake. Remove the buffer layer and repeat the extraction with 25-milliliter portions of buffer at least three times and any additional times that may be necessary to insure complete extraction of the antibiotic. Combine the extractives and make the proper estimated dilutions in 10-percent potassium phosphate buffer pH 6.0, to give a concentration of 10 units per milliliter (estimated).

(ii) The standard curve is prepared in the following concentrations: 6, 7, 8, 9, 10, 11, 12, 13, 14, and 15 units per milliliter in 10-percent potassium phosphate buffer, pH 6.0. The 10 units per milliliter concentration is used as the reference point. Its content of polymyxin is satisfactory if it contains not less than 85 percent of the number of units per gram that it is represented to contain.

(4) *Neomycin content.* Proceed as directed in § 141e.410 (b) (1) of this chapter, with the following exceptions:

(i) In lieu of the directions for the preparation of the sample described in § 141e.410 (b) (1) (vii) of this chapter, prepare the sample as directed in subparagraph (1) (i) of this paragraph or by a blending technique as follows: Place a convenient sized representative quantity of the sample in a blending jar containing 1.0 milliliter of a 0.3-percent aqueous solution of dioctyl sodium sulfosuccinate and sufficient 0.1 *M* potassium phosphate buffer, pH 8.0, to give a volume of 200 milliliters. Using a high-speed blender, blend for 5 minutes and then make the appropriate estimated dilutions with buffer.

(ii) Use as the test organism the Food and Drug Administration dihydrostreptomycin- (and streptomycin-) resistant strain of M. pyogenes var. aureus (P. C. I. 1209 R. D.) which is grown and maintained on media containing 1,000 micrograms of dihydrostreptomycin per milliliter of agar. Its content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram that it is represented to contain.

(b) *Moisture*. Proceed as directed in § 141a.8 (b) of this chapter.

PART 141c—CHLORTETRACYCLINE (OR TETRACYCLINE) AND CHLORTETRACYCLINE- (OR TETRACYCLINE-) CONTAINING DRUGS; TESTS AND METHODS OF ASSAY

Sec.
141c.201 Chlortetracycline hydrochloride.
141c.202 Chlortetracycline ointment (chlortetracycline hydrochloride ointment), chlortetracycline calcium ointment, chlortetracycline calcium cream; tetracycline hydrochloride ointment (tetracycline hydrochloride in oil suspension).
141c.203 Chlortetracycline troches, tetracycline hydrochloride troches.
141c.204 Chlortetracycline capsules (chlortetracycline hydrochloride capsules); tetracycline hydrochloride capsules; tetracycline capsules.
141c.205 Chlortetracycline powder (chlortetracycline hydrochloride powder); tetracycline hydrochloride powder; tetracycline powder.
141c.206 Chlortetracycline ophthalmic; tetracycline hydrochloride ophthalmic.
141c.207 Chlortetracycline tablets; tetracycline tablets.
141c.208 Chlortetracycline otic, tetracycline hydrochloride otic.
141c.209 Chlortetracycline dental cones.
141c.210 Chlortetracycline dental paste.
141c.211 Chlortetracycline surgical powder (chlortetracycline hydrochloride surgical powder); tetracycline hydrochloride surgical powder.
141c.212 Chlortetracycline suppositories (chlortetracycline hydrochloride suppositories); tetracycline hydrochloride suppositories.
141c.213 Chlortetracycline gauze packing.
141c.214 Chlortetracycline dressing.
141c.215 Chlortetracycline with vasoconstrictor.
141c.217 Chlortetracycline calcium oral drops, chlortetracycline calcium syrup; tetracycline syrup.
141c.218 Tetracycline hydrochloride.
141c.219 Crude chlortetracycline oral veterinary.
141c.220 Tetracycline.
141c.221 Tetracycline hydrochloride for intramuscular use.
141c.222 Tetracycline hydrochloride oral suspension; tetracycline calcium oral suspension.
141c.223 Chlortetracycline-neomycin-streptomycin-penicillin ointment; chlortetracycline-neomycin-dihydrostreptomycin-penicillin ointment; tetracycline hydrochloride-neomycin-streptomycin-penicillin ointment; tetracycline hydrochloride-neomycin-dihydrostreptomycin-penicillin ointment.
141c.224 Tetracycline hydrochloride-nystatin capsules.
141c.225 Tetracycline hydrochloride-nystatin tablets.
141c.226 Tetracycline and vascoconstrictor suspension.
Sec.
141c.227 Chlortetracycline spray dressing (chlortetracycline hydrochloride spray dressing).

AUTHORITY: §§ 141c.201 to 141c.227 issued under sec. 701, 52 Stat. 1055; 21 U. S. C. 371. Interpret or apply sec. 507, 59 Stat. 463, as amended; 21 U. S. C. 357.

§ 141c.201 *Chlortetracycline hydrochloride*—(a) *Potency*—(1) *Cylinders (cups)*. Use cylinders described under § 141a.1 (a) of this chapter.

(2) *Culture media*. Use a medium described under § 141a.1 (b) (1) and (2) of this chapter for the seed layer and the base layer. Use a nutrient broth described under § 141a.1 (b) (3) of this chapter for preparing a suspension of the test organism.

(3) *Working standard*. Weigh out carefully an appropriate amount of the chlortetracycline working standard and dilute to 1,000 micrograms per milliliter in water. The standard solution, when refrigerated, may be used for 7 days. The standard solution may be preserved for at least 2 months by freezing in small aliquots. Each aliquot should be sufficient for one day's use only.

(4) *Preparation of sample*. Dissolve the sample to be tested in sterile distilled water to make an appropriate stock solution. Make the final dilution in 1 percent phosphate buffer pH 6.0 to contain 20 micrograms per milliliter.

(5) *Preparation of suspension*. The test organism is Sarcina lutea (P. C. I. 1001 and American Type Culture Collection 9341). Maintain the test organism on slants of nutrient agar prepared as in subparagraph (2) of this paragraph, and transfer to a fresh agar slant once a week. Prepare a suspension of the test organism as follows: Streak an agar slant heavily with a test organism. Wash the growth off with 3 milliliters of nutrient broth. Use the suspension so obtained to inoculate the surface of a Roux bottle containing 300 milliliters of the nutrient agar. Spread the suspension over the entire surface with the aid of sterile glass beads. Incubate for 24 hours at 26° C. Wash growth from the agar surface with 25 milliliters of nutrient broth prepared as in subparagraph (2) of this paragraph. If an aliquot of this bulk suspension, when diluted with nutrient broth 1:10, gives 10 percent light transmission in a suitable photoelectric colorimeter equipped with a filter having a wave length of 6500 Angstrom units, the bulk suspension is satisfactory for use. It may be necessary to adjust the bulk suspension by dilution so that an aliquot of the adjusted suspension diluted 1:10 gives 10 percent of light transmission. (The adjusted bulk suspension only and not the 1:10 dilution of it is used in preparing the seed layer.) The bulk suspension may be used for at least one week. Add 0.5 to 1.0 milliliter of the adjusted bulk suspension to 100 milliliters of agar which has been melted and cooled to 48° C.

(6) *Preparation of plates*. Add 21 milliliters of the agar prepared as in subparagraph (2) of this paragraph to each Petri dish (20 x 100 millimeter). Distribute the agar evenly in the plates and allow it to harden. Use the plates the same day they are prepared. Add 4.0 milliliters of the inoculum as prepared in subparagraph (5) of this paragraph to each plate, tilting the plates back and forth to spread the inoculated agar evenly over the surface.

(7) *Assay*. Place six cylinders on the inoculated agar surface so that they are at approximately 60° intervals on a 2.8-centimeter radius. Use three plates for each sample. Fill three cylinders on each plate with the 20 micrograms per milliliter standard and three cylinders with the 20 micrograms per milliliter (estimated) sample, alternating standard and sample. At the same time prepare a standard curve using concentrations of the standard of 8.0, 10.0, 12.0, 16.0, 20.0, 24.0, 28.0, 32.0, and 36.0 micrograms per milliliter in 1 percent phosphate buffer pH 6.0. A total of 24 plates is used in the preparation of this standard curve, three plates for each solution, except the 20 micrograms per milliliter solution. The latter concentration is used as the reference point and is included on each plate. On each of three plates fill three cylinders with the 20 micrograms per milliliter standard and the other three cylinders with the concentration of the standard under test. Thus, there will be 72 twenty-microgram determinations and nine determinations for each of the other points on the curve. Incubate the plates for 16 to 18 hours at 32° C.–35° C. and measure the diameter of each circle of inhibition. Average the readings of the 20 micrograms per milliliter concentration and the readings of the point tested for each set of three plates and average also all 72 readings of the 20 micrograms per milliliter concentration. The average of the 72 readings and the 20 micrograms per milliliter concentration is the correction point for the curve. Correct the average value obtained for each point to the figure it would be if the 20 micrograms per milliliter reading for that set of three plates were the same as the correction point. Thus, if in correcting the 16 micrograms per milliliter concentration the average of the 72 readings of the 20 micrograms per milliliter concentration is 18.0 millimeters, and the average of the 20 micrograms per milliliter concentration of this set of three plates is 17.8 millimeters, the correction is +0.2 millimeter. If the average reading of the 16 micrograms per milliliter concentration of those same three plates is 17.0 millimeters, the corrected value is then 17.2 millimeters.

Plot these corrected values, including the average of the 20 micrograms per milliliter concentration on two-cycle semilog paper, using the concentration in micrograms per milliliter as the ordinate (the logarithmic scale) and the diameter of the zone of inhibition as the abscissa. Draw the standard curve through these points.

To estimate the potency of the sample, average the zone readings of the standard and the zone readings of the sample on the three plates used. If the sample gives a larger zone size than the average of the standard, add the difference between them to the 20 micrograms per milliliter unit zone on the standard curve. If the average value is lower than the standard value, subtract the difference between them from the micrograms per milliliter unit value on the curve. From the curves read the potencies corresponding to these corrected values of zone sizes.

(8) *Turbidimetric assay.* In lieu of the plate assay method described above, the sample may be assayed for potency by the following turbidimetric method:

(i) *Test culture and media.* Employ the agar described in § 141a.1 (b) of this chapter for maintaining the test organism which is M. pyogenes var. aureus (P. C. 209-P and American Type Culture Collection 6538-P). Transfer the organism to fresh agar slants and incubate at 32° C.-35° C. overnight. For use in the assay, suspend daily the growth from a fresh slant in a small amount of nutrient broth prepared as in § 141a.1 (b) (3) of this chapter and transfer to a flask containing sufficient nutrient broth warmed to 37° C. (about 150 milliliters) to give a light transmission reading of 85 percent using a filter at 6,500 Angstrom units in a photoelectric colorimeter. Prepare the daily inoculum by adding 40 milliliters of this suspension to each liter of nutrient broth needed for the test.

(ii) *Working standard and solutions.* Prepare a standard stock solution as described in subparagraph (3) of this paragraph, or dissolve a weighed portion of working standard in $M/10$ monopotassium phosphate buffer pH 4.5 to contain 10 micrograms per milliliter. Small aliquots, each sufficient for a day's test, if kept frozen, may be used for at least two months.

To prepare solutions for the standard curve, make further dilutions of the stock solution to contain 0.1 microgram per milliliter in phosphate buffer solution. To a triplicate series of 16 millimeter x 125 millimeter tubes (outside dimension), add 0.1, 0.2, 0.3, 0.4, 0.5, 0.6, 0.7, 0.8, 0.9, and 1.0 milliliter, respectively, of the 0.1 microgram per milliliter solution. Adjust volumes of all tubes to 1.0 milliliter with the buffer solution.

To prepare solutions for use in adjusting the photoelectric colorimeter, dilute the stock solution of the working standard to 1.0 microgram per milliliter and add 1.0 milliliter of this solution to each of 10 tubes. To another series of 10 tubes add 1.0 milliliter of the $M/10$ monopotassium phosphate buffer, pH 4.5.

To each of all the above tubes add 9.0 milliliters of inoculated broth described in subdivision (i) of this subparagraph and place immediately in a water bath at 37° C. for 3 to 4 hours. Then add 0.5 milliliter of formalin diluted 1:3 to each tube.

(iii) *Preparation of sample.* Dilute sample under test with $M/10$ monopotassium phosphate buffer pH 4.5 to contain 0.06 microgram per milliliter (estimated). (The stock solution may be prepared in distilled water.) Add 1.0 milliliter of this dilution to each of three 16 millimeter x 125 millimeter tubes (outside dimension). Add 9.0 milliliters of inoculated broth described in subdivision (i) of this subparagraph to each tube and place immediately in a 37° C. water bath for 3 to 4 hours. After incubation add 0.5 milliliter of formalin diluted 1:3 to each tube and read the percent light transmission in a photoelectric colorimeter, using a broad band filter having a light transmission of 5,800 Angstrom units.

(iv) *Estimation of potency.* Average the light transmission readings for each concentration of the standard. Plot these values on cross-section paper using average light transmission readings as the ordinate and chlortetracycline concentrations in micrograms per tube as the abscissa. Prepare the standard curve by connecting successive points with a straightedge. Since the final concentration of chlortetracycline per milliliter of broth is equivalent to the concentration per milliliter of the standard solution used, the latter concentrations for each concentration level of the standard may be expressed as percent and substituted on the abscissa of the standard curve. Thus the 0.06 microgram concentration is 100 percent, the 0.05 microgram concentration 83.3 percent, etc. If this is done the percent potency of the sample under test may be read directly from the standard curve.

(9) *Colorimetric assay.* In lieu of the assay methods described above, the sample may be assayed by the following colorimetric method: Prepare an aqueous solution of 0.5 milligram per milliliter of the sample to be assayed. Transfer two 2.0-milliliter aliquots to each of two 50-milliliter volumetric flasks. Add 5.0 milliliters of 2 N HCl to one flask and 5.0 milliliters of distilled water to the other flask as a control blank. Heat both flasks in a boiling water bath for 5 minutes, then cool the flasks under tap water, add 5.0 milliliters of 2 N HCl to the control blank and immediately make up to mark with distilled water. Transfer the solutions to 1.0-centimeter colorimetric cells, set the photoelectric colorimeter at 100 percent light transmission for the blank, using a 440-mμ filter. Then replace this with the cell containing the unknown and read the percent transmission. Determine the concentration of the unknown solution by reference to a standard curve prepared by treating appropriate aliquots of a standard solution of pure chlortetracycline hydrochloride as described above.

(10) *Chlortetracycline content.* The potency of chlortetracycline is satisfactory, when assayed by the methods described in this section, if the immediate containers contain 85 percent of the number of grams they are represented to contain.

(b) *Sterility.* Using 40 milligrams from each container tested, proceed as directed in § 141a.2 of this chapter, except that neither penicillinase nor the control tube is used in the test for bacteria.

(c) *Toxicity.* Proceed as directed in § 141a.4 of this chapter, using a test dose 0.5 milliliter of an aqueous solution containing 2 milligrams per milliliter, except if it is intend for use solely in the manufacture of a veterinary drug for nonparenteral use, use a test dose of 0.4 milliliter of such solution.

(d) *Pyrogens.* Proceed as directed in § 141a.3 of this chapter, using a test dose 1.0 ml. per kilogram of an aqueous solution containing 5 milligrams per milliliter.

(e) *Histamine.* Proceed as directed in § 141b.105 of this chapter, using as a test dose 0.6 milliliter of a solution containing 5 milligrams per milliliter prepared with the diluent recommended by the manufacturer in his labeling for the drug.

(f) *Moisture.* Proceed as directed in §141a.5 (a) or § 141a.26 (e) of this chapter.

(g) *pH.* Proceed as directed in § 141a.5 (b) of this chapter, using an aqueous solution containing 10 milligrams per milliliter.

(h) *Microscopical test for crystallinity.* Proceed as directed in § 141a.5 (c) of this chapter.

§ 141c.202 *Chlortetracycline ointment (chlortetracycline hydrochloride ointment), chlortetracycline calcium ointment, chlortetracycline calcium cream; tetracycline hydrochloride ointment (tetracycline hydrochloride in oil suspension)*—(a) *Potency.* If it is tetracycline hydrochloride ointment proceed as directed in § 141c.218 (a), and if it is chlortetracycline ointment proceed as directed in § 141c.201 (a), except § 141c.201 (a) (10), and in lieu of the directions in § 141c.201 (a) (4) and (8) (iii) prepare the sample as follows: Accurately weigh the container and contents and place 0.5 to 1.0 gram into a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Reweigh the container to obtain weight of ointment used in test. Shake ointment and ether until homogeneous. Shake with a 25-milliliter portion of the buffer solution. Remove the buffer layer and repeat the extraction with three 25-milliliter quantities of buffer. Combine the extracts and make the proper estimated dilutions in the buffer solution. The sample may also be prepared by placing an accurately weighed sample consisting of 0.5-1.0 gram into a glass blending jar containing 200 milliliters of the buffer solution. Using a high-speed blender, blend the mixture for approximately 3 minutes and make proper estimated dilutions in the buffer solution. The potency of the ointment is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.8 (b) of this chapter.

§ 141c.203 *Chlortetracycline troches; tetracycline hydrochloride troches*—(a) *Potency.* If it is tetracycline hydrochloride proceed as directed in § 141c.218 (a), and if it is chlortetracycline hydrochloride troches proceed as directed in § 141c.201 (a), except § 141c.201 (a) (10), and in lieu of the directions in § 141c.201 (a) (4) and (8) (iii) prepare the sample as follows: Place 12 troches in a glass blending jar containing 500 milliliters of sterile distilled water. Using a high-speed blender, blend for 3 to 5 minutes and then make the proper estimated dilutions in the buffer solution. The average potency of the troches is satisfactory if they contain not less than 85 percent of the number of milligrams they are represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

§ 141c.204 *Chlortetracycline capsules (chlortetracycline hydrochloride capsules); tetracycline hydrochloride capsules; tetracycline capsules*—(a) *Potency.* Using 3 capsules of 250 milligrams or 5 capsules of 50 milligrams or 100 milligrams and 500 milliliters of water in the blender, proceed as directed in § 141c.203 (a) if it is chlortetracycline. If it is tetracycline hydrochloride or tetracycline, use 500 milliliters of 0.01 *N* HCl (if it contains vitamins use 500 milliliters of 0.1 *N* HCl), and proceed as directed in § 141c.218 (a). If it contains vegetable oils, use 1 milliliter of a 10-percent aqueous solution of polysorbate 80 and sufficient solvent to give 500 milliliters. The average potency of the drug is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a) or § 141a.26 (e) of this chapter.

§ 141c.205 *Chlortetracycline powder (chlortetracycline hydrochloride powder); tetracycline hydrochloride powder; tetracycline powder*—(a) *Potency.* Using a 3.0-gram sample or the entire contents of the immediate container for each determination, proceed as directed in § 141c.203 (a) if it is chlortetracycline powder. If it is tetracycline powder, blend a 3.0-gram sample as directed in § 141c.203 (a), or reconstitute in the immediate container as directed in the labeling of the drug. Transfer an appropriate aliquot of 1.0 milliliter to 5.0 milliliters to a 100-milliliter volumetric flask and make to mark with 0.01 *N* HCl. Withdraw an aliquot from the volumetric flask and dilute to 0.24 microgram per milliliter, using *M*/10 phosphate buffer at pH 4.5, and proceed as directed in § 141c.218 (a). The average potency of the powder is satisfactory if it contains not less than 85 percent of the number of milligrams of chloreteracycline or tetracycline hydrochloride or tetracycline per gram or per immediate container that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

§ 141c.206 *Chlortetracycline ophthalmic; tetracycline hydrochloride ophthalmic*—(a) *Potency.* If it is tetracycline hydrochloride ophthalmic, proceed as directed in § 141c.218 (a); if it is chlortetracycline ophthalmic, proceed as directed in § 141c.201 (a). Its potency is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

(c) *Sterility.* Proceed as directed in § 141a.2 of this chapter except that:

(1) Do not use penicillinase or the control tube in the test for bacteria.

(2) In lieu of the last sentence of § 141a.2 (b) of this chapter, the batch meets the requirements of the test for bacteria if no tube shows growth.

(3) In lieu of the last sentence of § 141a.2 (c) of this chapter, the batch meets the requirements of the test for molds and yeasts if no tube shows growth.

(d) *pH.* Proceed as directed in § 141a.5 (b) of this chapter, using a solution prepared as directed in the labeling of the drug.

§ 41c.207 *Chlortetracycline tablets; tetracycline tablets*—(a) *Potency.* Proceed as directed in § 141c.204 (a). The average potency of the drug is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a) or § 141a.26 (e) of this chapter.

§ 141c.208 *Chlortetracycline otic, tetracycline hydrochloride otic*—(a) *Potency.* If it is chlortetracycline proceed as directed in § 141c.201 (a), and if it is tetracycline hydrochloride proceed as directed in § 141c.218 (a).

(b) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

§ 141c.209 *Chlortetracycline dental cones*—(a) *Potency.* Proceed as directed in § 141c.203 (a), using 500 milliliters of distilled water to prepare the sample. The average potency of the cone is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

§ 141c.210 *Chlortetracycline dental paste*—(a) *Potency.* Proceed as directed in § 141c.203 (a), using an accurately weighed sample of approximately 2.0 grams and blend in 200 cubic centimeters of sterile distilled water. The potency of chlortetracycline dental paste is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.8 (b) of this chapter.

§ 141c.211 *Chlortetracycline surgical powder (chlortetracycline hydrochloride surgical powder); tetracycline hydrochloride surgical powder*—(a) *Potency.* If it is chlortetracycline proceed as directed in § 141c.201 (a), and if it is tetracycline hydrochloride proceed as directed in § 141c.218 (a).

(b) *Sterility.* Proceed as directed in § 141b.108 (c) of this chapter.

(c) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

§ 141c.212 *Chlortetracycline suppositories (chlortetracycline hydrochloride suppositories); tetracycline hydrochloride suppositories*—(a) *Potency.* If they are tetracycline hydrochloride suppositories, proceed as directed in § 141c.218 (a); and if they are chlortetracycline suppositories, proceed as directed in § 141c.201 (a), except subparagraph (10) of that paragraph, and in lieu of the directions in subparagraphs (4) and (8) (iii) of § 141c.201 (a) prepare the sample as follows: Place three suppositories into a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake the suppositories and ether until homogeneous. Shake with a 50-milliliter portion of the buffer solution. Remove the buffer layer and repeat the extraction with three 50-milliliter quantities of buffer. Combine the extracts and centrifuge an aliquot at 2,000 r. p. m. for 5 minutes. Remove an aliquot of the supernatant and make the proper estimated dilutions in the buffer solution. The average potency of the suppository is satisfactory if it contains not less than 85 percent of the number of milligrams of chlortetracycline or tetracycline hydrochloride that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.8 (b) of this chapter.

§ 141c.213 *Chlortetracycline gauze packing*—(a) *Potency.* Using three packings, obtain the average weight and average linear length per packing. Assay three packings by dissolving each in 500 milliliters of 0.1 *N* HCl and allow to soak with frequent agitation for not less than 2 hours. Use aliquots of these solutions and proceed as directed in § 141c.201 (a). Calculate the average potency per gram and per linear foot. The average potency of the gauze packing is satisfactory if it contains not less than 85 percent of the number of milligrams per gram and per linear foot it is represented to contain.

(b) *Sterility.* Using individual gauze packings, proceed as directed in § 141a.2 of this chapter, except that neither penicillinase nor the control tube is used in the test for bacteria.

(c) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

§ 141c.214 *Chlortetracycline dressing*—(a) *Potency.* Using individual dressings and appropriate volumes of peroxide-free ether and buffer solution, proceed as directed in § 141c.202 (a).

(b) *Sterility.* Using approximately one-fourth of each individual dressing tested, proceed as directed in § 141a.2 of this chapter, except that neither penicillinase nor the control tube is used in the test for bacteria.

(c) *Moisture.* Proceed as directed in § 141a.8 (b) of this chapter.

§ 141c.215 *Chlortetracycline with vasoconstrictor*—(a) *Potency.* Proceed as directed in § 141c.201 (a).

(b) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

§ 141c.217 *Chlortetracycline calcium oral drops; chlortetracycline calcium syrup; tetracycline syrup*—(a) *Potency.* If it is chlortetracycline calcium oral drops or chlortetracycline calcium syrup, proceed as directed in § 141c.201 (a), and if it is tetracycline syrup use 1.0-milliliter aliquots of the sample and proceed as directed in § 141c.205 (a). Its potency is satisfactory if each milliliter of the drug contains not less than 85 percent of the number of milligrams of chlortetracycline or tetracycline that it is represented to contain.

(b) *pH.* Using the undiluted sample, proceed as directed in § 141a.5 (b) of this chapter.

(c) *Toxicity.* Administer orally, by means of a cannula or other suitable device, to each of 5 mice, within the weight range of 18 to 25 grams, a sufficient volume of the preparation to contain 25 milligrams if it is chlortetracycline or 12.5 milligrams, if it is tetracycline. If no animal dies within 48 hours, the sample is nontoxic. If one or more animals die within 48 hours, repeat the test with 5 unused mice weighing 20 grams (±0.5

gram) each; if all animals survive the repeat test the sample is nontoxic.

§ 141c.218 *Tetracycline hydrochloride*—(a) *Potency.* Use the tetracycline hydrochloride working standard as a standard of comparison and proceed as directed in § 141c.201 (a) (8), except:

(1) Prepare the standard stock solution by dissolving an appropriate amount of the working standard in sufficient 0.01 *N* HCl to give a concentration of 1,000 micrograms per milliliter. This stock solution may be kept in the refrigerator for 1 week. Do not freeze.

(2) Further dilute the stock solution to contain 0.4 microgram per milliliter in *M*/10 monopotassium phosphate buffer pH 4.5 in lieu of 0.1 microgram per milliliter.

(3) Prepare 10 tubes each of the minimum (0.04 microgram per milliliter) and maximum (0.4 microgram per milliliter) concentrations diluted for the standard curve, and use these solutions to adjust the photoelectric colorimeter.

(4) Use the 0.24 microgram per milliliter concentration of the standard curve as the reference point.

(5) Dissolve the sample to be tested in sufficient 0.01 *N* HCl to give an appropriate stock solution. Further dilute in *M*/10 monopotassium phosphate buffer pH 4.5 to give an estimated concentration of 0.24 microgram per milliliter in lieu of 0.06 microgram per milliliter. The potency of tetracycline hydrochloride for intravenous use is satisfactory if each immediate container contains not less than 90 percent of tetracycline hydrochloride that it is represented to contain.

(b) *Sterility and toxicity.* Proceed as directed in § 141c.201 (b) and (c).

(c) *Pyrogens.* Proceed as directed in § 141a.3 of this chapter, using as a test dose 1.0 milliliter per kilogram of an aqueous solution containing 500 micrograms per milliliter.

(d) *Histamine, moisture, pH, and crystallinity.* Proceed as directed in § 141c.201 (e), (f), and (g) and § 141a.5 (c) of this chapter.

(e) *Extinction coefficient.* Dissolve approximately 40 milliliters of the sample, accurately weighed, in approximately 150 milliliters of distilled water by mixing thoroughly. Dilute to exactly 250 milliliters with distilled water and mix thoroughly. Transfer a 10.0-milliliter aliquot of this solution to a 100-milliliter volumetric flask, add about 75 milliliters of distilled water and 5.0 milliliters of 5 *N* NaOH, and then make to 100 milliliters with water and mix thoroughly. Exactly 6 minutes after the addition of the NaOH, determine the absorbency of the solution at 380 mμ compared with distilled water as a blank. Use a suitable spectrophotometer for the absorbency measurements.

$$E_{1\text{ cm.}}^{1\%} \text{ of the sample} = \frac{\text{Absorbancy at 380 m}\mu \times 25{,}000}{\text{Weight of sample in milligrams}}$$

§ 141c.219 *Crude chlortetracycline oral veterinary*—(a) *Potency.* Accurately weigh approximately 3.0 grams of the sample and place in a blender jar containing 200 milliliters of an acid-acetone solution prepared with 1 part 4 *N* HCl, 6 parts distilled water, and 13 parts acetone. Blend for 3 minutes. Using an aliquot of the liquid, make the proper estimated dilutions in *M*/10 monopotassium phosphate buffer pH 4.5, shake well, and proceed as directed in § 141c.201 (a) (8). Its content of chlortetracycline is satisfactory if it contains not less than 85 percent of the number of grams that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

§ 141c.220 *Tetracycline*—(a) *Moisture.* Proceed as directed in § 141a.26 (e) of this chapter. Use the value obtained to calculate the weighed samples used in paragraphs (b), (c), and (f) of this section to the anhydrous compound.

(b) *Potency.* Using 40 milligrams (as the anhydrous compound) of sample, proceed as directed in § 141c.218 (a).

(c) *Toxicity.* Proceed as directed in § 141b.103 of this chapter, using as a test dose 0.5 milliliter of an aqueous solution containing 2.0 milligrams per milliliter prepared by dissolving 40 milligrams (as the anhydrous compound) in 2.0 milliliters of 0.1 *N* HCl and diluting with the required amount of water.

(d) *pH.* Proceed as directed in § 141a.5 (b) of this chapter, using an aqueous suspension prepared by adding 10 milligrams per milliliter.

(e) *Crystallinity.* Proceed as directed in § 141a.5 (c) of this chapter.

(f) *Extinction coefficient.* Proceed as directed in § 141c.218 (e), except dissolve 40 milligrams (as the anhydrous compound) in 2.0 milliliters 0.1 *N* HCl and dilute to 250 milliliters with distilled water.

§ 141c.221 *Tetracycline hydrochloride for intramuscular use*—(a) *Potency.* Reconstitute the sample as directed on the label or labeling. Using a suitable syringe, withdraw a one-dose aliquot and place in a 100-milliliter volumetric flask. Make to mark with 0.01 *N* HCl, and proceed as directed in § 141c 218 (a). Its potency is satisfactory if the immediate container contains not less than 90 percent of the number of milligrams of tetracycline hydrochloride that it is represented to contain.

(b) *Sterility.* Proceed as directed in § 141c.201 (b).

(c) *Pyrogens.* Proceed as directed in § 141c.218 (c).

(d) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

(e) *pH.* Proceed as directed in § 141a.5 (b) of this chapter, using an aqueous solution containing 10 milligrams of tetracycline hydrochloride per milliliter.

§ 141c.222 *Tetracycline hydrochloride oral suspension; tetracycline hydrochloride oral solution; tetracycline calcium oral suspension*—(a) *Potency.* Transfer 1 milliliter of the well-shaken suspension to a suitable high-speed blender containing 500 milliliters of 0.01 *N* HCl (if it contains vitamins, use 0.1 *N* HCl). Blend for 5 minutes and proceed as directed in § 141c.218 (a). Its potency is satisfactory if it contains not less than 85 percent of the number of milligrams, or the equivalent number of milligrams, of tetracycline hydrochloride per milliliter that it is represented to contain.

(b) *Moisture.* If it is tetracycline hydrochloride oral suspension or tetracycline hydrochloride oral solution, proceed as directed in § 141a.7 (c) of this chapter.

(c) *pH.* If it is tetracycline hydrochloride oral solution or tetracycline calcium oral suspension, use the undiluted drug and proceed as directed in § 141a.5 (b) of this chapter.

§ 141c.223 *Chlortetracycline-neomycin-streptomycin-penicillin ointment; chlortetracycline - neomycin - dihydrostreptomycin-penicillin ointment; tetracycline hydrochloride-neomycin-streptomycin-penicillin ointment; tetracycline hydrochloride-neomycin-dihydrostreptomycin-penicillin ointment*—(a) *Potency*—(1) *Penicillin content.* Place an accurately weighed sample of approximately 1 gram in an extraction funnel prepared by fusing a ground-glass joint to the top of a medium-porosity sintered-glass filter funnel (30-millimeter diameter). Wash with five 10-milliliter portions of warm iso-octane and draw off the ointment base under vacuum. Discard the iso-octane washings. Wash the residue with three 10-milliliter portions of chloroform and draw off under vacuum, combine the extracts, and make to mark in a 250-milliliter volumetric flask with absolute alcohol. Make the proper estimated dilutions in 1-percent phosphate buffer, at pH 6.0, and proceed as directed in § 141a.1 of this chapter. Its content of penicillin is satisfactory if it contains not less than 85 percent of the number of units per gram of ointment that it is represented to contain.

(2) *Chlortetracycline content.* Wash the residue in the funnel four times with 10-milliliter portions of 0.3 percent piperidine in acetone solution. Withdraw each washing under vacuum. Combine the four washings in a 100-milliliter volumetric flask and make to mark with acetone. Remove an aliquot of this solution and proceed as directed in § 141c.201 (a) (8). Its content of chlortetracycline is satisfactory if it contains not less than 85 percent of the number of milligrams per gram of ointment that it is represented to contain.

(3) *Tetracycline hydrochloride content.* Prepare the sample as directed in subparagraph (2) of this paragraph and proceed as directed in § 141c.218. Its content of tetracycline hydrochloride is satisfactory if it contains not less than 85 percent of the number of milligrams per gram of ointment that it is represented to contain.

(4) *Neomycin content.* The residue remaining in the funnel after the extraction described in subparagraph (2) of this paragraph contains the neomycin and streptomycin or dihydrostreptomycin. Wash this residue five times, using 10-milliliter aliquots of distilled water, drawing each washing off under vacuum. Combine the washings in a 100-milliliter

volumetric flask and make to mark with distilled water. Using an aliquot of this aqueous solution, proceed as directed in § 141a.65 (a) (2) (ii) or (iii) of this chapter. The content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram of ointment that it is represented to contain.

(5) *Streptomycin content.* Using an aliquot of the aqueous solution prepared in subparagraph (4) of this paragraph, proceed as directed in § 141b.101 (a) through (i) of this chapter. The content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram of ointment that it is represented to contain.

(6) *Dihydrostreptomycin content.* Using an aliquot of the aqueous solution prepared in subparagraph (4) of this paragraph, and the dihydrostreptomycin working standard as a standard of comparison, proceed as directed in § 141b.101 (a) through (i) of this chapter. The content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per gram of ointment that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.8 (b) of this chapter.

§ 141c.224 *Tetracycline hydrochloride-nystatin capsules*—(a) *Capsules*—(1) *Potency*—(i) *Tetracycline hydrochloride content.* Proceed as directed in § 141c.204 (a) for tetracycline hydrochloride capsules. Its content of tetracycline hydrochloride is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(ii) *Nystatin content.* Prepare the sample for assay by placing 5 capsules in a blending jar with 150 milliliters of formamide. Blend for 2 minutes in a high-speed blender and then dilute an aliquot with sufficient formamide to give a concentration of 400 units per milliliter (estimated). Further dilute this solution with 1-percent phosphate buffer, pH 6.0, to give a concentration of 20 units per milliliter (estimated). Assay as directed in paragraph (b) of this section. Its content of nystatin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(iii) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

(b) *Nystatin used in making the capsules*—(1) *Potency*—(i) *Cylinders (cups).* Use cylinders described in § 141a.1 (a) of this chapter.

(ii) *Culture media.* Use ingredients that conform to the standards, if any, prescribed by the U. S. P. or N. F.

(*a*) Make nutrient agar for carrying the organism and for preparing the inoculated agar plates as follows:

Peptone	6 grams.
Yeast extract	3 grams.
Beef extract	1.5 grams.
Sodium chloride	10 grams.
Dextrose	10 grams.
Agar	15 grams.
Distilled water to make	1,000 milliliters.

pH 6.0 to 6.2 after sterilization.

(*b*) Make nutrient broth for preparing an inoculum of the test organism:

Peptone	10 grams.
Dextrose	20 grams.
Distilled water to make	1,000 milliliters.

pH 5.6 to 5.7 after sterilization.

In lieu of preparing the media from the individual ingredients as specified, they may be prepared from a dehydrated mixture which, when reconstituted with distilled water, has the same composition as such media. Minor modifications of the specified individual ingredients are permissible if the resulting media possess growth-promoting properties at least equal to the media described.

(iii) *Working standard.* Dissolve a suitable weighed quantity of the working standard (obtained from the Food and Drug Administration) in sufficient formamide to give a stock solution containing 1,000 units per milliliter. This stock solution may be used for 3 days when stored at 5° C. or less.

(iv) *Preparation of sample.* Dissolve the sample to be tested in sufficient formamide to give a nystatin concentration of 400 units per milliliter (estimated). Further dilute with 1-percent phosphate buffer, pH 6.0, to 20 units per milliliter (estimated).

(v) *Preparation of test organism.* The test organism is Saccharomyces cervisiae (American Type Culture Collection 9763) which is maintained on slants of agar described under subdivision (ii) (*a*) of this subparagraph and transferred once a week. After transfer, the culture is incubated at 37° C. for 24 hours and then kept refrigerated. Prepare the organism suspension by either of the following methods:

(*a*) Inoculate 100 milliliters of the broth medium described under subdivision (ii) (*b*) of this subparagraph with a loopful of growth from the agar slant. Incubate the broth for 16 to 18 hours at 37° C. This broth culture may be used for several weeks if kept refrigerated.

(*b*) Wash the organism from the agar slant with 3 milliliters of sterile physiological saline solution onto a large agar surface such as that provided by a Roux bottle containing 300 milliliters of the agar described in subdivision (ii) (*a*) of this subparagraph. Spread the suspension of organisms over the entire agar surface with the aid of sterile glass beads. Incubate for 24 hours at 37° C. and then wash the resulting growth from the agar surface with about 15 milliliters of sterile physiological saline solution. This suspension may be used for several weeks if kept refrigerated. Run test plates to determine the quantity of this broth culture (usually about 2.5 milliliters) or saline suspension (usually about 0.1 milliliter) that should be added to each 100 milliliters of agar to give clear, sharp inhibitory zones of appropriate size.

(vi) *Preparation of plates.* Melt a sufficient amount of the agar described in subdivision (ii) (*a*) of this subparagraph, cool to 48° C., add the proper amount of the test organism as described above, and mix thoroughly, Add 6 milliliters of this inoculated agar to each Petri dish (100 millimeters x 22 millimeters, with flat bottom). Distribute the agar evenly in the plates, cover with porcelain covers glazed on the outside, and allow to harden. After the agar has hardened, place 6 cylinders on the agar surface so that they are at approximately 60° intervals on a 2.8-centimeter radius.

(vii) *Standard curve.* Dilute aliquots of the 1,000 units per milliliter standard stock solution with formamide to give concentrations of 100, 200, 300, 400, 600, and 800 units per milliliter. Dilute these formamide solutions and the stock solution with 1-percent phosphate buffer, pH 6.0, to make concentrations of 5, 10, 15, 20, 30, 40, and 50 units per milliliter, respectively. A total of 18 plates is used in the preparation of the standard curve, three plates for each solution, except the 20 units per milliliter solution. The latter concentration is used as the reference point and is included on each plate. On each of the three plates fill three cylinders with the 20 units per milliliter standard and the other three cylinders with the concentration of the standard concentration under test. Thus, there will be 54 twenty-unit determinations and nine determinations for each of the other concentrations on the curve. Incubate the plates for 16 to 18 hours at 37° C. and measure the diameter of each zone of inhibition. Average the readings of the 20 units per milliliter concentration and the readings of the concentration tested for each set of three plates, and average also all 54 readings of the 20 units per milliliter concentration. The average of the 54 readings of the 20 units per milliliter concentration is the correction point for the curve. Correct the average value obtained for each point to the figure it would be if the 20 units per milliliter reading for that set of three plates were the same as the correction point. Thus, if in correcting the 16 units per milliliter concentration the average of the 54 readings of the 20 units per milliliter concentration is 16.0 millimeters and the average of the 20 units per milliliter concentration of this set of three plates is 15.8 millimeters, the correction is +0.2 millimeter. If the average reading of the 15 units per milliliter concentration of those same three plates is 15.0 millimeters, the corrected value is then 15.2 millimeters. Plot these corrected values, including the average of the 20 units per milliliter concentration on two-cycle semilog paper, using the concentration in micrograms per milliliter as the ordinate (the logarithmic scale) and the diameter of the zone of inhibition as the abscissa. Draw the standard curve through these points.

(viii) *Assay.* Use 3 plates for each sample. Fill three cylinders on each plate with the 20 units per milliliter standard and three cylinders with the 20 units per milliliter (estimated) sample, alternating standard and sample. Incubate the plates for 16 to 18 hours at 37° C. and then measure the diameter of each zone of inhibition. To estimate the potency of the sample, average the zone readings of the standard and the zone readings of the sample on the three plates used. If the sample gives a larger zone size than the average of the standard, add the difference between them to the 20 units per milliliter zone on the standard curve. If the average value is lower than the standard value, subtract the difference between them from the 20 units per milliliter value on the curve. From the curves read the potencies corresponding to these corrected values of zone sizes.

(2) *Toxicity.* Inject intraperitoneally each of 5 mice, within the weight range of 18 grams to 25 grams, with 0.5 milliliter of a suspension of the drug containing 1,200 units per milliliter in a 0.5 percent acacia solution. If no animal dies within 48 hours, the sample is nontoxic. If one or more of the animals die within 48 hours, repeat the test with 5 unused mice weighing 20 grams (±0.5 gram) each; if all animals survive the repeat test, the sample is nontoxic.

(3) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

(4) *pH.* Proceed as directed in § 141a.5 (b) of this chapter, using a 3-percent aqueous suspension of the drug.

(5) *Optical rotation.* Accurately weigh approximately 1.0 gram of the sample in a 25-milliliter glass-stoppered volumetric flask, dissolve the sample and dilute to volume with dimethyl formamide at 20° C. Transfer the solution to a 200-millimeter tube, determine the angular rotation in a suitable polarimeter, using sodium light or a 5,893 angstrom unit filter, and calculate the specific rotation.

§ 141c.225 *Tetracycline hydrochloride-nystatin tablets*—(a) *Tablets*—(1) *Potency*—(i) *Tetracycline hydrochloride content.* Proceed as directed in § 141c.224 (a) (1) (i). Its content of tetracycline hydrochloride is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(ii) *Nystatin content.* Proceed as directed in § 141c.224 (a) (1) (ii). Its content of nystatin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(iii) *Moisture.* Proceed as directed in § 141a.5 (a) or § 141a.26 (e) of this chapter.

(b) *Nystatin used in making the tablets.* Proceed as directed in § 141c.224 (b).

§ 141c.226 *Tetracycline and vasoconstrictor suspension*—(a) *Potency.* Proceed as directed in § 141c.218 (a). Its potency is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(b) *pH.* Using the undiluted sample, proceed as directed in § 141a.5 (b) of this chapter.

§ 141c.227 *Chlortetracycline spray dressing (chlortetracycline hydrochloride spray dressing)*—(a) *Potency.* Spray the entire contents of the well shaken sample into a large tared beaker. Place in a vacuum desiccator, evacuate, and allow to stand at room temperature for 16 to 18 hours. After the gas has volatilized, accurately weigh the beaker and contents and determine the weight of the ointment ejected when used as directed in its labeling. Remove a representative quantity (usually 1 gram) of the oinment from the beaker, accurately determine its weight, and place in a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Proceed as directed in § 141c.202 (a). The content of the immediate container is satisfactory if it contains not less than 85 percent of the number of grams of ointment that it is represented to contain. The potency of the ointment is satisfactory if it contains not less than 85 percent of the number of milligrams of chlortetracycline hydrochloride per gram that it is represented to contain.

(b) *Sterility.* Using an amount of spray (usually 5 to 8 seconds) equivalent to approximately 40 milligrams of chlortetracycline from each container tested, proceed as directed in § 141a.2 of this chapter, except that neither penicillinase nor the control tube is used in the test for bacteria.

(c) *Moisture.* Proceed as directed in § 141a.8 (b) of this chapter.

PART 141d—CHLORAMPHENICOL AND CHLORAMPHENICOL-CONTAINING DRUGS; TESTS AND METHODS OF ASSAY

Sec.
141d.301 Chloramphenicol.
141d.302 Chloramphenicol capsules; potency.
141d.303 Chloramphenicol ointment; potency.
141d.304 Chloramphenicol ophthalmic.
141d.305 Chloramphenicol palmitate.
141d.306 Chloramphenicol palmitate oral suspension.
141d.307 Chloramphenicol solution; chloramphenicol for aqueous injection.
141d.308 Chloramphenicol otic; chloramphenicol topical.
141d.309 Chloramphenicol-streptomycin capsules; chloramphenicol-dihydrostreptomycin capsules.
141d.310 Chloramphenicol tablets.
141d.311 Chloramphenicol palmitate-streptomycin oral suspension; chloramphenicol palmitate-dihydrostreptomycin oral suspension.

AUTHORITY: §§ 141d.301 to 141d.311 issued under sec. 701; 52 Stat. 1055; 21 U. S. C. 371. Interpret or apply sec. 507, 59 Stat. 463, as amended; 21 U. S. C. 357.

§ 141d.301 *Chloramphenicol*—(a) *Potency*—(1) *Cylinders (cups).* Use cylinders described under § 141a.1 (a) of this chapter.

(2) *Culture media.* Use the medium described under § 141a.1 (b) (1) of this chapter for both the seed layer and the base layer. Use the nutrient broth described under § 141a.1 (b) (3) of this chapter for preparing a suspension of the test organism.

(3) *Working standard.* Prepare the working standard by weighing out carefully appropriate amounts of the chloramphenicol working standard and dilute in 1 percent phosphate buffer pH 6.0 to give a solution containing 50 micrograms per milliliter. Keep this stock solution at a temperature of 15° C or less and use for only 1 month. The standard may first be dissolved in a small amount of ethyl alcohol to facilitate solution.

(4) *Preparation of sample.* Prepare the sample to be tested by dissolving in a small amount of ethyl alcohol and then further dilute in 1 percent phosphate buffer pH 6.0 to make an appropriate stock solution.

(5) *Preparation of suspension.* The test organism is Sarcina lutea (P. C. I. 1001). Maintain the test organism on slants of nutrient agar prepared as in subparagraph (2) of this paragraph and transfer to a fresh agar slant once a week. Prepare a suspension of the test organism as follows: Streak an agar slant heavily with the test organism. Wash the growth off in about 3 milliliters of nutrient broth. Use the suspension so obtained to inoculate the surface of a Roux bottle containing 300 milliliters of the nutrient agar. Spread the suspension over the entire surface with the aid of sterile glass beads. Incubate for 24 hours at 26° C. Wash the growth from the agar surface with 20 milliliters of nutrient broth prepared as in subparagraph (2) of this paragraph. If an aliquot of this bulk suspension, when diluted with nutrient broth 1:10, gives a 10 percent light transmission in a suitable photoelectric colorimeter equipped with a filter having a wave length of 6500 Angstrom units, it is satisfactory for use. It may be necessary to adjust the bulk suspension by dilution so that an aliquot of the adjusted suspension diluted 1:10 gives 10 percent light transmission. (The adjusted bulk suspension only, and not the 1:10 dilution of it, is used in preparing the seed layer.) The bulk suspension may be used in the test for 1 month. Add 1 to 1.5 milliliters of the adjusted bulk suspension to 100 milliliters of agar which has been melted and cooled to 48° C.

(6) *Preparation of plates.* Add 21 milliliters of the agar prepared as in subparagraph (2) of this paragraph to each Petri dish (20 x 100 millimeters). Distribute the agar evenly in the plates and allow it to harden. Use the plates the same day they are prepared. Add 4 milliliters of the inoculum prepared as in subparagraph (5) of this paragraph for each plate, tilting the plates back and forth to spread the inoculated agar evenly over the surface.

(7) *Assay.* Place six cylinders on the inoculated agar surface so that they are at approximately 60° intervals on a 2.8-centimeter radius. Use three plates for each sample. Fill three cylinders on each plate with the 50 micrograms per milliliter standard and three cylinders with the 50 micrograms per milliliter (estimated) sample, alternating standard and sample. At the same time prepare a standard curve, using concentrations of the standard of 30.0, 35.0, 40.0, 45.0, 50.0, 55.0, 60.0, 65.0, and 70.0 micrograms per milliliter. A total of 24 plates is used in the preparation of the standard curve, three plates for each solution except the 50 micrograms per milliliter solution. The latter concentration is used as the reference point and is included on each plate. On each of three plates fill three cylinders with the 50 micrograms per milliliter standard and the other three cylinders with the concentration of the standard under test.

Thus, there will be seventy-two 50-microgram determinations and nine determinations for each of the other points on the curve. Incubate the plates for 16 to 18 hours at 32° C.–35° C. and measure the diameter of each circle of inhibition. Average the readings of the 50 micrograms per milliliter concentration and the readings of the point tested for each set of three plates, and average also all 72 readings of the 50 micrograms per milliliter concentration. The average of the 72 readings of the 50 micrograms per milliliter concentration is the correction point for the curve. Correct the average value obtained for each point to the figure it would be if the 50 micrograms per milliliter readings for that set of three plates were the same as the correction point. Thus, if in correcting the 40 micrograms per milliliter concentration the average of the 72 readings of the 50 micrograms per milliliter is 18.0 millimeters, and the average of the 50 micrograms per milliliter concentration of this set of three plates is 17.8 millimeters, the correction is 0.2 millimeter. If the average reading of the 40 micrograms per milliliter concentration of these same three plates is 17.0 millimeters, the corrected concentration of these same three plates is 17.0 millimeters, the corrected value is then 17.2 millimeters.

Plot these corrected values, including the average of the 50 micrograms per milliliter concentrations on two-cycle semilog paper, using the concentration in micrograms per milliliter as the ordinate (the logarithmic scale) and the diameter of the zone of inhibition as the abscissa. Draw the standard curve through these points.

To estimate the potency of the sample, average the zone readings of the standard and the zone readings of the sample on the three plates used. If the sample gives a larger zone size than the average of the standard, add the difference between them to the 50 micrograms per milliliter unit zone on the standard curve. If the average value is lower than the standard value, subtract the difference between them from the 50 micrograms per milliliter unit value on the curve. From the curves read the potencies corresponding to these corrected values of zone sizes.

(8) *Spectrophotometric method.* In lieu of the plate-assay method described above, the following method may be used:

Dissolve 20 milligrams of the sample, accurately weighed, in 100 milliliters of distilled water, warming to hasten solution. Cool to room temperature, dilute to exactly 1,000 milliliters with distilled water, and mix. With a suitable spectrophotometer determine the optical density of the solution in a 1-centimeter cell at 278 mμ compared with distilled water as a blank. Multiply the optical density figure obtained by the appropriate factor to obtain the optical density value of a 1 percent solution.

The $E^{1\%}_{1\,\mathrm{cm.}}$ value of the sample multiplied by 100, divided by 298 represents the percent potency.

(9) *Chloramphenicol content.* The potency of chloramphenicol is satisfactory, when assayed by the methods described in this section, if the immediate containers contain 85 percent of the number of grams they are represented to contain.

(b) *Sterility.* Proceed as directed in § 141c.201 (b) of this chapter.

(c) *Toxicity.* Proceed as directed in § 141a.4 of this chapter, using as a test dose 0.5 milliliter of a solution containing 2 milligrams per milliliter. Use physiological salt solution as the diluent.

(d) *Pyrogens.* Proceed as directed in § 141a.3 of this chapter, using as a test dose 1.0 milliliter per kilogram of a solution containing 5 milligrams per milliliter. Use physiological salt solution as the diluent.

(e) *Histamine.* Proceed as directed in § 141b.105 of this chapter, using as a test dose 0.6 milliliter of a solution containing 5 milligrams per milliliter prepared by application of heat.

(f) *pH.* Proceed as directed in § 141a.5 (b) of this chapter using a saturated aqueous solution.

(g) *Specific rotation.* Accurately weigh approximately 1.25 grams of the sample in a 25-milliliter glass-stoppered volumetric flask and dissolve in about 15 milliliters with absolute alcohol, warming if necessary. Dilute the solution to 25 milliliters with absolute alcohol and mix thoroughly. Transfer the solution to a 200-millimeter tube, determine the angular rotation in a suitable polarimeter, using sodium light or a 5893 Angstrom filter, and calculate the specific rotation.

(h) *Melting point.* Proceed as directed by the U. S. P.

(i) *Extinction coefficient.* Proceed as directed in paragraph (a) (8) of this section.

§ 141d.302 *Chloramphenicol capsules; potency*—(a) *Bioassay method.* Proceed as directed in § 141d.301 (a), except subparagraphs (8) and (9) of that paragraph, and in lieu of the directions in subparagraph (4) prepare the sample as follows: Place the contents of not less than 10 capsules and the empty capsules in 100 milliliters of ethyl alcohol, and using a high-speed blender, blend for approximately 2 minutes. To the blender, add 400 milliliters of 1.0-percent phosphate buffer, pH 6.0, and blend for approximately 2 minutes. Withdraw a 1.0-milliliter aliquot and make the proper estimated dilutions in 1.0-percent phosphate buffer, pH 6.0.

(b) *Spectrophotometric assay method.* Place the contents of 10 capsules in a 250-milliliter volumetric flask. Add 50 milliliters of redistilled methanol to the flask and shake for at least 1 minute. Make to volume with distilled water and mix thoroughly. Withdraw an aliquot and dilute with sufficient distilled water to give a concentration of 20 micrograms per milliliter. With a suitable spectrophotometer, determine the optical density of this solution in a 1-centimeter cell at 278 mμ compared with distilled water as a blank.

$$\text{Potency per capsule} = \frac{\text{optical density}}{0.596} \times \text{labeled potency per capsule}$$

(c) *Chloramphenicol content.* When assayed by either of these methods, its potency is satisfactory if it contains not less than 85 percent of the number of milligrams of chloramphenicol per capsule that it is represented to contain.

§ 141d.303 *Chloramphenicol ointment; potency.* Proceed as directed in § 141d.301 (a), except § 141d.301 (a) (8) and (9), and in lieu of the directions in § 141d.301 (a) (4) prepare the sample by one of the following methods:

(a) Place an accurately weighed representative sample (usually 1.0 gram of the ointment) in a blending jar containing 1 milliliter of a 10-percent aqueous solution of polysorbate 80 and sufficient 1-percent phosphate buffer at pH 6.0 to make 100 milliliters. Using a high-speed blender, blend the mixture for 2 minutes and make the proper estimated dilutions in 1-percent phosphate buffer at pH 6.0.

(b) Place a representative sample (0.5 gram) in a separatory funnel containing 10 milliliters of peroxide-free ether. Shake the separatory funnel vigorously to bring about complete mixing of the ointment and ether. Shake with a 15-milliliter portion of 1-percent phosphate buffer at pH 6.0. Remove the buffer layer and repeat the extraction with two additional 15-milliliter portions of buffer. Combine the extractives and dilute to 50 milliliters with 1-percent phosphate buffer. Make the proper estimated dilutions in 1-percent phosphate buffer at pH 6.0.

The potency of chloramphenicol ointment is satisfactory if it contains not less than 85 percent of the number of milligrams per gram that it is represented to contain.

§ 141d.304 *Chloramphenicol ophthalmic*—(a) *Potency.* Proceed as directed in § 141d.301 (a), except subparagraph (9) thereof. The potency of chloramphenicol ophthalmic is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(b) *pH.* Proceed as directed in § 141a.5 (b) of this chapter, using a solution prepared as directed in the labeling of the drug.

(c) *Sterility.* Proceed as directed in § 141a.2 of this chapter, except that:

(1) Use 0.5 milliliter of the suspension of the sample prepared according to label directions, and do not use penicillinase or the control tube in the test for bacteria.

(2) In lieu of the last sentence of § 141a.2 (b) of this chapter, the batch meets the requirements of the test for bacteria if no tube shows growth.

(3) In lieu of the last sentence of § 141a.2 (c) of this chapter, the batch meets the requirements of the test for molds and yeasts if no tube shows growth.

§ 141d.305 *Chloramphenicol palmitate*—(a) *Potency.* Dissolve 50 milligrams of the sample in absolute ethanol and make to 100 milliliters in a volumetric flask with absolute ethanol. Transfer a 5-milliliter aliquot to another 100-milliliter volumetric flask and make to volume with absolute ethanol. With a suitable spectrophotometer determine the optical density of the solution in a 1-centimeter cell at 271 mμ compared with absolute ethanol as a blank. Multiply the optical-density figure obtained by the appropriate factor to obtain the optical density value of 1-percent solution. The $E_{1\,\text{cm.}}^{1\%}$ value of the sample multiplied by 575, divided by 178, represents the micrograms per milligram of chloramphenicol.

(b) *Toxicity.* Administer orally, by means of a cannula or other suitable device, to each of 5 mice, within the weight range of 18 to 25 grams, 1.0 milliliter of a suspension of the drug containing 60 milligrams per milliliter in 10-percent acacia solution. If no animal dies within 48 hours, the sample is nontoxic. If one or more animals die within 48 hours, repeat the test with 5 unused mice weighing 20 grams (±0.5 gram) each; if all animals survive the repeat test the sample is nontoxic.

(c) *Melting point.* Proceed as directed by the U. S. P.

(d) *Extinction coefficient.* Proceed as directed in paragraph (a) of this section.

§ 141d.306 *Chloramphenicol palmitate oral suspension*—(a) *Potency.* Using a hypodermic syringe, transfer 1.0 milliliter of the suspension to a separatory funnel containing 10 milliliters of water and 25 milliliters of chloroform. Shake for 1 minute, allow the layers to separate, and filter the lower chloroform layer through a pledget of cotton. Transfer a 1.0-milliliter portion of the clear chloroform filtrate to a 100-milliliter volumetric flask, make to volume with absolute ethanol, and mix. With a suitable spectrophotometer, determine the absorbance of this solution at 271 millimicrons, using as a blank 1.0 milliliter of chloroform U. S. P. diluted to 100 milliliters with absolute ethanol. The number of milligrams of chloramphenicol contained in each milliliter of chloramphenicol palmitate oral suspension is obtained by the following calculation:

$$C=\frac{A\times 25{,}000\times 0.575,}{178}$$

where:

C=the number of milligrams of chloramphenicol in 1.0 milliliter of the chloramphenicol palmitate suspension;
A=the absorbance of the solution at 271 millimicrons;
25,000=dilution factor;
0.575=the factor for converting chloramphenicol palmitate to chloramphenicol;
extinction coefficient of chloramphenicol palmitate at 271 millimicrons.

The potency of chloramphenicol palmitate oral suspension is satisfactory if it contains not less than 85 percent of the number of milligrams per milliliter that it is represented to contain.

(b) *pH.* Using the undiluted suspension, proceed as directed in § 141a.5 (b) of this chapter.

§ 141d.307 *Chloramphenicol solution; chloramphenicol for aqueous injection*—(a) *Potency*—(1) *Chloramphenicol solution.* Proceed as directed in § 141d.301 (a), except subparagraphs (8) and (9) of that paragraph, and in lieu of the directions in subparagraph (4) of that paragraph dilute the sample in sufficient 1.0-percent phosphate buffer pH 6.0 to make an appropriate stock solution.

(2) *Chloramphenicol for aqueous injection.* Proceed as directed in § 141d.301 (a), except subparagraph (9) of that paragraph, and in lieu of the directions in subparagraph (4) of that paragraph prepare the sample as follows: Add the amount of water indicated in the labeling of the drug to the vial, and shake well. Remove 1.0 milliliter of the suspension, transfer to a 50-milliliter volumetric flask, and make to volume with absolute alcohol. Quickly remove 1.0 milliliter and make to the proper estimated dilution in 1.0-percent phosphate buffer pH 6.0. In case the spectrophotometric method is used, proceed as follows: Add to the vial the amount of water indicated in the labeling of the drug and shake vigorously until a uniform suspension is obtained. Transfer an aliquot of this suspension, equivalent to 1.0 gram of chloramphenicol, to a 1,000-milliliter glass-stoppered volumetric flask, add about 500 milliliters of distilled water, and heat on a steam bath until solution of the chloramphenicol is complete (but no longer than 10 minutes). Cool to room temperature and dilute to exactly 1,000 milliliters with distilled water. Mix thoroughly, and transfer exactly 5 milliliters of this solution to a 250-milliliter glass-stoppered volumetric flask. Dilute to exactly 250 milliliters with distilled water and mix thoroughly. Measure the absorbency of this solution on a suitable spectrophotometer at 278 mμ against a blank of distilled water. The

$$\frac{\text{optical density at 278 m}\mu}{298}\times 500=\text{grams}$$

of chloramphenicol in the sample tested. (From this value calculate the quantity of chloramphenicol in the immediate container.)

Its potency is satisfactory when assayed by the methods described in this paragraph if it contains not less than 85 percent of the number of grams of chloramphenicol it is represented to contain.

(b) *Sterility.* If it is the solution, proceed as directed in § 141b.102 of this chapter. If it is the dry mixture of the drug, dissolve the entire contents of each vial to be tested in a sterile 40-percent solution (v/v) of N,N,dimethylacetamide, using 10 milliliters of the diluent for each 1.0 gram, and proceed as directed in § 141a.2 of this chapter, except that neither penicillinase nor the control tube is used in the test for bacteria.

(c) *Toxicity.* Proceed as directed in § 141d.301 (c).

(d) *Pyrogens.* Proceed as directed in § 141d.301 (d).

(e) *Histamine.* Proceed as directed in § 141d.301 (e).

(f) *pH.* Proceed as directed in § 141a.5 (b) of this chapter, using the undiluted drug in the case of the solution, and if it is the dry mixture of the drug use a suspension prepared as directed in its labeling.

§ 141d.308 *Chloramphenicol otic; chloramphenicol topical*—(a) *Potency.* Using 1.0 milliliter, proceed as directed in § 141d.303 (a). Its potency is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.7 (c) of this chapter.

(c) *pH.* Dilute the drug with an equal volume of distilled water and proceed as directed in § 141a.5 (b) of this chapter.

§ 141d.309 *Chloramphenicol-streptomycin capsules; chloramphenicol-dihydrostreptomycin capsules*—(a) *Potency*—(1) *Content of chloramphenicol.* Proceed as directed in § 141d.302 (a) or (b). Its content of chloramphenicol is satisfactory if it contains not less than 85 percent of the number of milligrams per capsule that it is represented to contain.

(2) *Content of streptomycin.* Using 10 capsules, proceed as directed in § 141b.101 of this chapter, except paragraphs (j) and (k) of that section. Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per capsule that it is represented to contain.

(3) *Content of dihydrostreptomycin.* Proceed as directed in subparagraph (2) of this paragraph, using the dihydrostreptomycin working standard as a standard of comparison. Its content of dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per capsule that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

§ 141d.310 *Chloramphenicol tablets*—(a) *Bioassay method.* Proceed as directed in § 141d.302 (a).

(b) *Spectrophotometric assay method.* Weigh accurately a counted number of not less than 10 tablets and determine the average weight per tablet. Reduce 10 tablets to a fine powder in a mortar and transfer an amount of powder containing 500 milligrams (estimated) of chloramphenicol to a 1,000-milliliter glass-stoppered volumetric flask. Add 50 milliliters of redistilled methanol to the flask and shake for at least 1 minute. Make to volume with distilled water and mix thoroughly. Transfer exactly 10 milliliters of this solution into a 250-milliliter glass-stoppered volumetric flask. Make to mark and mix thoroughly. Determine the absorbancy of this solution on a suitable spectrophotometer in a 1-centimeter quart cell at 278 millimicrons against a blank of distilled water.

$$\text{Milligrams of chloramphenicol per tablet}=\frac{\text{Absorbancy}\times 500\times\text{average weight in milligrams}}{0.596\times\text{weight of powder tested in milligrams}}$$

(c) *Chloramphenicol content.* When assayed by either of these methods, its potency is satisfactory if it contains not less than 85 percent of the number of milligrams of chloramphenicol per tablet that it is represented to contain.

§ 141d.311 *Chloramphenicol palmitate-streptomycin oral suspension; chloramphenicol palmitate-dihydrostreptomycin oral suspension*—(a) *Potency*—(1) *Chloramphenicol content.* Proceed as directed in § 141d.306 (a). Its content of chloramphenicol is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(2) *Steptomycin or dihydrostreptomycin content.* Proceed as directed in § 141b.101 of this chapter except § 141b.101 (b), and if it contains dihydrostreptomycin use the dihydrostreptomycin working standard as the standard of comparison. Its content of streptomycin or dihydrostreptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(b) *pH.* Using the undiluted suspension, proceed as directed in § 141a.5 (b) of this chapter.

PART 141e—BACITRACIN AND BACITRACIN-CONTAINING DRUGS; TESTS AND METHODS OF ASSAY

Sec.

141e.401 Bacitracin.
141e.402 Bacitracin ointment; zinc bacitracin ointment.
141e.403 Bacitracin tablets; zinc bacitracin tablets.
141e.404 Bacitracin troches; zinc bacitracin troches.
141e.405 Bacitracin with vasoconstrictor.
141e.406 Bacitracin-tyrothricin troches; zinc bacitracin-tyrothricin troches.
141e.407 Bacitracin-tyrothricin ointment.
141e.408 Bacitracin ophthalmic.
141e.409 Bacitracin-polymyxin ointment.
141e.410 Bacitracin-neomycin tablets; zinc bacitracin-neomycin tablets.
141e.411 Bacitracin-neomycin ointment.
141e.412 Bacitracin-polymyxin tablets.
141e.413 Bacitracin-neomycin troches; zinc bacitracin-neomycin troches.
141e.414 Bacitracin-neomycin with vasoconstrictor.
141e.415 Bacitracin-polymyxin troches; zinc bacitracin-polymyxin troches.
141e.416 Bacitracin methylene disalicylate.
141e.417 Powder bacitracin methylene disalicylate and streptomycin sulfate oral veterinary.
141e.418 Zinc bacitracin (bacitracin zinc salt).
141e.419 Bacitracin - neomycin - polymyxin troches; zinc bacitracin-neomycin-polymyxin troches.
141e.420 Bacitracin - tyrothricin - neomycin troches; zinc bacitracin-tyrothricin-neomycin troches; potency and moisture.
141e.421 Bacitracin - neomycin - polymyxin tablets.
141e.422 Bacitracin - polymyxin - neomycin ointment.
141e.423 Soluble bacitracin methylene disalicylate.
141e.424 Bacitracin - neomycin - polymyxin with vasoconstrictor.
141e.425 Bacitracin powder.
141e.426 Tablets bacitracin methylene disalicylate and streptomycin sulfate oral veterinary.

AUTHORITY: §§ 141e.401 to 141e.426 issued under sec. 701, 52 Stat. 1055; 21 U. S. C. 371. Interpret or apply sec. 507, 59 Stat. 463, as amended; 21 U. S. C. 357.

§ 141e.401 *Bacitracin*—(a) *Potency*—(1) *Plate assay.* Using the standard curve technique, proceed as directed in § 141a.1 (h) of this chapter, with the following exceptions:

(i) Use the bacitracin working standard and dissolve in 1-percent phosphate buffer to make an appropriate stock solution. The stock solution when refrigerated may be used for 2 weeks. The stock solution may also be preserved for at least 2 months by freezing in small aliquots. Each aliquot should be sufficient for 1 day's use only. Make all dilutions of the stock solution for the assay with 1-percent phosphate buffer.

(ii) Dissolve the sample to be tested in 1-percent phosphate buffer and make dilutions with the same solvent to one unit per milliliter (estimated).

(iii) The test organism is Micrococcus flavus, which is maintained at refrigerator temperature on slants of nutrient agar prepared as directed in § 141a.1 (b) (1) of this chapter. Inoculate a Roux bottle containing this agar from a stock slant of the organism and incubate 18 hours at 32° C.–35° C. Wash off the growth in 25 milliliters of sterile physiological saline solution. If an aliquot of this bulk suspension, when diluted 1:50 in physiological saline solution, gives 75 percent light transmission in a suitable photoelectric colorimeter equipped with a filter having a wave length of 6,500 Angstrom units, the bulk suspension is satisfactory for use. It may be necessary to adjust the bulk suspension by dilution so that an aliquot of the adjusted suspension diluted 1:50 gives 75 percent light transmission. (The adjusted bulk suspension only, and not the 1:50 dilution of it, is used in preparing the seed layer.) Add 0.3 to 0.5 milliliter of the adjusted bulk suspension to 100 milliliters of agar which has been melted and cooled to 48° C.

(2) *Turbidimetric assay.* In lieu of the plate-assay method described above, the sample may be assayed for potency by the following turbidimetric method:

(i) *Test culture and media.* Employ the agar described in § 141a.1 (b) (2) of this chapter (adjusted to a final pH 7.0) for maintaining the test organism, which is Staphylococcus aureus (PCI 1203). Transfer stock cultures every 2 weeks for test purposes. On the day of test transfer the growth from a stock slant to approximately 100 milliliters of nutrient broth (§ 141a.1 (b) (3) of this chapter). Incubate the inoculated broth until the culture has grown sufficiently to give a light transmission reading of 80–90 percent, using a filter having a light transmission peak at 6500 Angstrom units. This culture may be held overnight at refrigerator temperature if desired. Prepare the "daily" inoculum by adding approximately 6.0 milliliters of the standardized broth culture to each 100 milliliters of broth previously cooled to a temperature of approximately 15° C.

(ii) *Working-standard solutions.* Dilute the working standard to 10 units per milliliter of bacitracin in 1 percent phosphate buffer. Further dilute this to make solutions containing 0.100, 0.141, 0.200, 0.282, 0.398, and 0.562 units per milliliter. These solutions are used for preparing the standard curve and may be held at 15° C. for 1 week. Add 1.0 milliliter of each of these working standard solutions to each of six 16 millimeter by 125 millimeter tubes (outside dimension).

(iii) *Preparation of sample.* Dilute the sample under test to 0.25 unit per milliliter (estimated). Add 1.0 milliliter of the diluted sample to each of six 16 millimeter by 125 millimeter tubes (outside dimension). Add 9.0 milliliters of the "daily" inoculum described above to each tube of the standard and unknown series and place immediately in a 32° C. — 35° C. water bath for 4 hours. After incubation, add four drops of formalin to each tube, and estimate the turbidity of each in a photoelectric colorimeter, using a broad-band filter having a wave length of 5300 Angstrom units.

(iv) *Estimation of potency.* Average the six colorimeter readings at each standard level. Plot the average turbidity figures of the standard on semilog graph paper, employing units per tube as the abscissa (log scale) and light transmission as the ordinate. Connect the points with a straightedge. Average the sample readings and read in units per tube from the curve. Units per tube divided by 0.25×100 will give percent potency of the sample.

(3) *Bacitracin content.* The potency of bacitracin is satisfactory when assayed by the methods described in this section if the immediate containers contain not less than 85 percent and, if it is intended for systemic medication, not more than 115 percent of the number of units they are represented to contain.

(b) *Sterility.* Proceed as directed in § 141b.102 of this chapter.

(c) *Pyrogens.* Proceed as directed in § 141a.3 of this chapter, using as a test dose 1.0 milliliter per kilogram of a solution containing 300 units per milliliter. Use physiological salt solution as the diluent.

(d) *Toxicity.* Inject intravenously each of five mice within the weight range of 18–25 grams with 0.5 milliliter of a solution of the sample prepared by diluting with sterile physiological salt solution to 200 units per milliliter. The injection should be made over a period of not more than 5 seconds. If no animal dies within 48 hours, the sample is nontoxic. If one or more animals die within 48 hours, repeat the test with five unused mice weighing 20 grams (±0.5 gram) each. If all animals survive the repeat test the sample is nontoxic.

(e) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

(f) *pH.* Proceed as directed in § 141a.5 (b) of this chapter, using a solution containing 10,000 units per milliliter.

§ 141e.402 *Bacitracin ointment; zinc bacitracin ointment*—(a) *Potency.* Proceed as directed in § 141e.401 (a), except § 141e.401 (a) (3), and in lieu of the directions in § 141e.401 (a) (1) (iii), prepare the sample as directed in § 141a.8 (a) of this chapter. Its content of bacitracin or zinc bacitracin is satisfactory if it contains not less than 85 percent of the number of units per gram that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.8 (b) of this chapter.

§ 141e.403 *Bacitracin tablets; zinc bacitracin tablets*—(a) *Potency.* Proceed as directed in § 141e.401 (a), except § 141e.401 (a) (3), and in lieu of the directions in § 141e.401 (a) (1) (iii) place 5 tablets in a blending jar and add thereto 125 milliliters of 1-percent phosphate buffer pH 6.0. After blending for 1 minute with a high-speed blender, add an additional 125 milliliters of buffer to the blender. Blend again for 1 minute and make the proper estimated dilutions in 1-percent phosphate buffer pH 6.0. The content of bacitracin or zinc bacitracin is satisfactory if it contains not less than 85 percent of the number of units per tablet that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

§ 141e.404 *Bacitracin troches; zinc bacitracin troches*—(a) *Potency.* Proceed as directed in § 141e.403 (a). The average potency of the troche is satisfactory if it is not less than 85 percent of the number of units per troche that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

§ 141e.405 *Bacitracin with vasoconstrictor*—(a) *Potency.* Proceed as directed in § 141e.401 (a), except subparagraph (3) thereof. The potency of bacitracin with vasoconstrictor is satisfactory if it contains not less than 85 percent of the number of units per container it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

§ 141e.406 *Bacitracin - tyrothricin troches; zinc bacitracin-tyrothricin troches*—(a) *Potency.* Proceed as directed in § 141e.403 (a). Its content of bacitracin or zinc bacitracin is satisfactory if it contains not less than 85 percent of the number of units per troche that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

§ 141e.407 *Bacitracin-tyrothricin ointment.* Proceed as directed in § 141e.402. Its content of bacitracin is satisfactory if it contains not less than 85 percent of the number of units per gram it is represented to contain.

§ 141e.408 *Bacitracin ophthalmic*—(a) *Potency.* Proceed as directed in § 141e.401 (a).

(b) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

(c) *pH.* Proceed as directed in § 141a.5 (b) of this chapter, using a solution prepared as directed in the labeling for the drug.

(d) *Sterility.* Proceed as directed in § 141a.2 of this chapter, except that:

(1) Do not use penicillinase or the control tube in the test for bacteria.

(2) In lieu of the last sentence of § 141a.2 (b) of this chapter, the batch meets the requirements of the test for bacteria if no tube shows growth.

(3) In lieu of the last sentence of § 141a.2 (c) of this chapter, the batch meets the requirements of the test for molds and yeasts if no tube shows growth.

§ 141e.409 *Bacitracin-polymyxin ointment*—(a) *Potency*—(1) *Bacitracin content.* Proceed as directed in § 141e.402 (a). Its content of bacitracin is satisfactory if it contains not less than 85 percent of the number of units per gram that it is represented to contain.

(2) *Polymyxin content.* Proceed as directed in § 141b.112 (b) (1) of this chapter, except in lieu of the directions in subdivision (vii) for the preparation of the sample, prepare the sample as follows: Accurately weigh approximately 5 grams and transfer to a separatory funnel containing approximately 50 milliliters of peroxide-free ether. Shake with four 25-milliliter portions of 1.0-percent phosphate buffer (pH 6.0) and combine the extracts. Its content of polymyxin is satisfactory if it contains not less than 85 percent of the number of units per gram that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.8 (b) of this chapter.

§ 141e.410 *Bacitracin-neomycin tablets; zinc bacitracin-neomycin tablets*—(a) *Tablets*—(1) *Potency*—(i) *Bacitracin or zinc bacitracin content.* Proceed as directed in § 141e.403 (a). Its content of bacitracin or zinc bacitracin is satisfactory if it contains not less than 85 percent of the number of units per tablet that it is represented to contain.

(ii) *Neomycin content.* Place 5 tablets in a blending jar and add thereto 200 milliliters of a 500-milliliter quantity of 0.10-percent phosphate buffer pH 8.0. After blending for 1 minute with a high-speed blender, add the remainder of the buffer. Blend again for 1 minute and make the proper estimated dilutions in the buffer and proceed as directed in paragraph (b) (1) of this section. Its content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams of activity that it is represented to contain.

(2) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

(b) *Neomycin used in making the tablets*—(1) *Potency*—(i) *Cylinders (cups).* Use cylinders described under § 141a.1 (a) of this chapter.

(ii) *Culture medium.* Use the medium described in § 141a.1 (b) (1) of this chapter for both the base and seed layers, except its pH after sterilization is 7.8 to 8.0.

(iii) *Working standard.* Dry the working standard (obtained from the Food and Drug Administration) for 3 hours at 60° C. and a pressure of 5 millimeters or less and weigh out a sufficient quantity to make a convenient stock solution by diluting with a 0.1 *M* potassium phosphate buffer, pH 7.8 to 8.0 The stock solution, when stored at a temperature of approximately 15° C., or less, may be used for a period not exceeding 1 month.

(iv) *Standard curve.* Prepare daily from the stock solution a standard curve as directed in § 141b.101 (d) of this chapter, using solutions of the neomycin working standard in 0.1 *M* potassium phosphate buffer, pH 7.8 to 8.0, in concentrations of 4.0, 6.0, 8.0, 10.0, 12.0, 15.0, and 20.0 micrograms per milliliter. The 10.0 micrograms per milliliter concentration is used as the reference point.

(v) *Preparation of test organism.* The test organism is M. pyogenes var. aureus (P. C. I. 209-P or American Type Culture Collection 6538P) which is maintained on agar described in § 141a.1 (b) (1) of this chapter. From a stock slant inoculate a Roux bottle containing this same agar and incubate for 24 hours at 32° C. to 35° C. Wash the resulting growth from the agar surface with about 100 milliliters of sterile distilled water. Standardize this suspension by determining the dilution which will permit 80 percent light transmission through a filter at 6500 Angstrom units in a photoelectric colorimeter. The suspension may be used for 2 weeks, if it is stored at a temperature of 15° C. or less.

(vi) *Preparation of plates.* Using the agar described in subdivision (ii) of this subparagraph and approximately a 0.5 percent inoculum of the suspension described in subdivision (v) of this subparagraph, prepare the plates as directed in § 141a.1 (e) of this chapter.

(vii) *Assay.* Dissolve volumetrically in 0.1 *M* potassium phosphate buffer, pH 7.8 to 8.0, the sample to be tested to make a convenient stock solution. Further dilute volumetrically this solution with 0.1 *M* potassium phosphate buffer, pH 7.8 to 8.0, to a final concentration of 10.0 micrograms (estimated) per milliliter and proceed as directed in § 141b.101 (h) and (i) of this chapter.

(2) *Toxicity.* Proceed as directed in § 141a.4 of this chapter, using 0.5 milliliter of a solution prepared by diluting the sample to approximately 200 micrograms per milliliter with physiological salt solution.

(3) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

(4) *pH.* Proceed as directed in § 141a.5 (b) of this chapter, using a solution containing 33 milligrams per milliliter.

§ 141e.411 *Bacitracin-neomycin ointment; zinc bacitracin-neomycin ointment*—(a) *Potency*—(1) *Bacitracin or zinc bacitracin content.* Proceed as directed in § 141e.402 (a). Its content of bacitracin or zinc bacitracin is satisfactory if it contains not less than 85 percent of the number of units per gram that it is represented to contain.

(2) *Neomycin content.* Prepare the sample as directed in § 141a.8 (a) of this chapter, except in lieu of potassium phosphate buffer use 0.10 *M* phosphate buffer (pH 7.8–8.0) and proceed as directed in § 141e.410 (b) (1). Its content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.8 (b) of this chapter.

§ 141e.412 *Bacitracin-polymyxin tablets*—(a) *Potency*—(1) *Bacitracin content.* Proceed as directed in § 141e.403 (a). Its content of bacitracin is satisfactory if it contains not less than 85 percent of the number of units it is represented to contain.

(2) *Polymyxin content.* Using an aliquot of the solution prepared in accordance with subparagraph (1) of this paragraph, proceed as directed in § 141b.112 (a) (1) (ii) of this chapter. Its content of polymyxin is satisfactory if it contains not less than 85 percent of the

number of units it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

§ 141e.413 *Bacitracin-neomycin troches; zinc bacitracin-neomycin troches*—(a) *Potency*—(1) *Content of bacitracin and zinc bacitracin.* Proceed as directed in § 141e.404 (a). Its content of bacitracin or zinc bacitracin is satisfactory if it contains not less than 85 percent of the number of units per troche that it is represented to contain.

(2) *Neomycin content.* Proceed as directed in § 141e.410 (a) (1) (ii). Its content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

§ 141e.414 *Bacitracin-neomycin with vasoconstrictor*—(a) *Potency*—(1) *Bacitracin content.* Proceed as directed in § 141e.405 (a). Its content of bacitracin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(2) *Neomycin content.* Proceed as directed in § 141e.410 (b) (1). Its content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

§ 141e.415 *Bacitracin-polymyxin troches; zinc bacitracin-polymyxin troches*—(a) *Potency*—(1) *Polymyxin content.* Dissolve 5 troches in a small amount of 1-percent phosphate buffer pH 6.0, then add sufficient buffer to give a concentration of 100 units per milliliter and proceed as directed in § 141b.112 (b) (1) of this chapter. Its content of polymyxin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(2) *Content of bacitracin and zinc bacitracin.* Using an aliquot of the solution prepared in subparagraph (1) of this paragraph, proceed as directed in § 141e.401 (a) (1). Its content of bacitracin or zinc bacitracin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

§ 141e.416 *Bacitracin methylene disalicylate*—(a) *Potency.* Proceed as directed in § 141e.401 (a) (1), except in lieu of the directions for preparing the sample in § 141e.401 (a) (1) (ii) prepare the sample as follows: Place an accurately weighed sample of approximately 1 gram in a blending jar, add 99 milliliters of an aqueous solution of 2-percent sodium bicarbonate and 1 milliliter of a 10-percent aqueous solution of polysorbate 80 and blend for 3 minutes in a high-speed blender. Allow the foam to subside, remove an aliquot of the solution, and dilute to 1 unit per milliliter with 1-percent phosphate buffer.

(b) *Toxicity.* Proceed as directed in § 141d.305 (b) of this chapter, using as the test dose 1 milliliter of a suspension containing 1,000 units of bacitracin activity per mouse.

(c) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

(d) *pH.* Proceed as directed in § 141a.5 (b) of this chapter, using a saturated aqueous solution containing approximately 50 milligrams per milliliter.

§ 141e.417 *Powder bacitracin methylene disalicylate and streptomycin sulfate oral veterinary*—(a) *Potency*—(1) *Bacitracin content.* Proceed as directed in § 141e.401 (a), except in lieu of the directions for preparing the sample in § 141e.401 (a) (1) (ii), prepare the sample as follows: Place an accurately weighed sample of approximately 5 grams in a blending jar, add 40 milliliters of 2.0-percent sodium bicarbonate and swirl until the sample is thoroughly wetted. Allow to stand for 15 minutes with occasional swirling. After standing for 15 minutes, add 30 milliliters of 1-percent potassium phosphate buffer at pH 6.0 and allow to stand for 1 hour, with occasional swirling. Add 30 milliliters of acetone and blend for 2 minutes; allow to stand for 2 minutes and reblend for 2 minutes. Allow to settle for 15 minutes, and filter through filter paper on a Buchner funnel. Remove an aliquot of the filtrate and add sufficient semicarbazide 1.0-percent solution, at pH 6.5–7.0, to inactivate (1 hour at room temperature) the streptomycin contained in the solution. After inactivation, remove an aliquot of this solution and dilute to 1 unit per milliliter with 1.0-percent phosphate buffer. Its potency is satisfactory if it contains not less than 85 percent of the units of bacitracin activity that it is represented to contain.

(2) *Streptomycin content.* Proceed as directed in § 141b.101 of this chapter. Its content of streptomycin is satisfactory if it contains not less than 85 percent of the number of milligrams of streptomycin activity per gram that it is represented to contain.

(b) *Moisture.* Using a 1.0-gram sample, proceed as directed in § 141a.5 (a) of this chapter.

§ 141e.418 *Zinc bacitracin (bacitracin zinc salt)*—(a) *Potency.* Proceed as directed in § 141e.401 (a) (1), except prepare the sample as follows: Suspend an accurately weighed sample of approximately 100 milligrams in 5 milliliters of distilled water. Add 0.5 milliliter of 3 *N* HCl, stir until the sample is dissolved, and transfer to a 100-milliliter volumetric flash and make to volume with distilled water. Dilute an aliquot of this solution to 1.0 unit per milliliter (estimated) with 1-percent phosphate buffer.

(b) *Toxicity.* Administer orally, by means of a cannula or other suitable device, to each of 5 mice within the weight range of 18-25 grams, 0.5 milliliter of a water suspension of the drug containing 4,000 units per milliliter. If no animal dies within 48 hours, the sample is nontoxic. If one or more animals die within 48 hours, repeat the test with 5 unused mice weighing 20 grams (±0.5 gram each); if all animals survive the repeat test, the sample is nontoxic.

(c) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

(d) *pH.* Prepare a saturated solution, using approximately 100 milligrams of the sample per milliliter, and proceed as directed in § 141a.5 (b) of this chapter.

(e) *Zinc content*—(1) *Reagents*—(i) *8-hydroxyquinoline.* Dissolve 5.0 grams of 8-hydroxyquinoline in 12 milliliters of acetic acid. Dilute to 100 milliliters with distilled water and filter if not clear. Do not use this solution if it is 2 weeks old.

(ii) *Ammonium acetate solution (approximately 2 N).* Dissolve 150–160 grams of ammonium acetate in 1 liter of distilled water and filter if not clear.

(iii) *10-percent acetic acid.* Add 1 part of acetic acid to 9 parts of water.

(2) *Procedure.* Accurately weigh approximately 500 milligrams of the sample in a 400-milliliter beaker. Dissolve the sample in 5 milliliters of 10-percent acetic acid and dilute to about 100 milliliters with distilled water. Heat the solution to 70° C.–90° C. and then add 10 milliliters of the 8-hydroxyquinoline reagent. Slowly add the ammonium acetate solution until a pH of 4.9–5.1 is reached (usually about 20 milliliters is required). Heat just below the boiling point for 2–5 minutes and then allow to cool for 30–60 minutes. Filter through a tared Gooch crucible, wash the precipitate thoroughly with distilled water, and dry to constant weight at 130° C.–140° C. Calculate the percentage of zinc content as follows:

$$\text{Percent zinc} = \frac{\text{weight of precipitate} \times 18.49}{\text{weight of sample in milligrams}}$$

§ 141e.419 *Bacitracin-neomycin-polymyxin troches; zinc bacitracin-neomycin-polymyxin troches*—(a) *Potency*—(1) *Neomycin content.* Proceed as directed in § 141e.410 (a) (1) (ii). Its content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams of activity that it is represented to contain.

(2) *Polymyxin content.* Proceed as directed in § 141e.415 (a) (1), except calculate from the quantity of neomycin found (using the method prescribed in subparagraph (1) of this paragraph) the quantity of neomycin that would be present when the sample is diluted to contain 100 units of polymyxin (labeled potency) per milliliter. Prepare the polymyxin standard curve by adding this calculated quantity of neomycin to each concentration of polymyxin used for the curve. Use this standard curve to calculate the polymyxin content of the sample. Its content of polymyxin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(3) *Content of bacitracin or zinc bacitracin.* Using an aliquot of the solution prepared in subparagraph (2) of this paragraph, proceed as directed in § 141e.401 (a) (1). Its content of bacitracin or zinc bacitracin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

§ 141e.420 *Bacitracin-tyrothricin-neomycin troches; zinc bacitracin-tyrothricin-neomycin troches; potency and* *moisture.* Proceed as directed in § 141e.413 (a) and (b).

§ 141e.421 *Bacitracin-neomycin-polymyxin tablets*—(a) *Potency*—(1) *Bacitracin content.* Proceed as directed in § 141e.403 (a). Its content of bacitracin is satisfactory if it contains not less than 85 percent of the number of units per tablet that it is represented to contain.

(2) *Neomycin content.* Proceed as directed in § 141e.410 (a) (1) (ii). Its content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams of activity per tablet that it is represented to contain.

(3) *Polymyxin content.* Proceed as directed in § 141b.112 (a) (1) (ii) of this chapter, except calculate from the quantity of neomycin found (using the method prescribed in subparagraph (2) of this paragraph) the quantity of neomycin that would be present when the sample is diluted to contain 100 units of polymyxin (labeled potency) per milliliter. Prepare the polymyxin standard curve by adding this calculated quantity of neomycin to each concentration of polymyxin used for the curve. Use this standard curve to calculate the polymyxin content of the sample. Its content of polymyxin is satisfactory if it contains not less than 85 percent of the number of units per tablet that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

§ 141e.422 *Bacitracin-polymyxin-neomycin ointment*—(a) *Potency*—(1) *Bacitracin content.* Proceed as directed in § 141e.409 (a) (1). Its content of bacitracin is satisfactory if it contains not less than 85 percent of the number of units per gram that it is represented to contain.

(2) *Polymyxin content.* Proceed as directed in § 141e.409 (a) (2), except calculate from the quantity of neomycin found (using the method prescribed in subparagraph (3) of this paragraph) the quantity of neomycin that would be present when the sample is diluted to contain 100 units of polymyxin (labeled potency) per milliliter. Prepare the polymyxin standard curve by adding this calculated quantity of neomycin to each concentration of polymyxin used for the curve. Use this standard curve to calculate the polymyxin content of the sample. Its content of polymyxin is satisfactory if it contains not less than 85 percent of the number of units that it is represented to contain.

(3) *Neomycin content.* Proceed as directed in § 141e.411 (a) (2). Its content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.8 (b) of this chapter.

§ 141e.423 *Soluble bacitracin methylene disalicylate*—(a) *Potency.* Proceed as directed in § 141e.401 (a) (1), except in lieu of the directions for preparing the sample in § 141e.401 (a) (1) (ii) prepare the sample as follows: Place an accurately weighed sample of approximately 1 to 5 grams in a 100-milliliter volumetric flask, dissolve in water, and dilute to 100 milliliters with water. Dilute a suitable aliquot with 1-percent phosphate buffer to a concentration of 1 unit per milliliter. Its potency is satisfactory if it contains not less than 85 percent of the bacitracin activity per pound that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

(c) *pH.* Proceed as directed in § 141a.5 (b) of this chapter, using a solution containing 200 units per milliliter.

§ 141e.424 *Bacitracin-neomycin-polymyxin with vasoconstrictor*—(a) *Potency.* Prepare the drug as directed in its labeling and proceed as follows:

(1) *Bacitracin content.* Proceed as directed in § 141e.401 (a). Its content of bacitracin is satisfactory if it contains not less than 85 percent of the number of units per milliliter that it is represented to contain.

(2) *Neomycin content.* Proceed as directed in § 141e.410 (b) (1). Its content of neomycin is satisfactory if it contains not less than 85 percent of the number of milligrams per milliliter that it is represented to contain.

(3) *Polymyxin B content.* Proceed as directed in § 141b.112 (b) (1) of this chapter, except that:

(i) Calculate from the quantity of neomycin found (using the method prescribed in subparagraph (2) of this paragraph) (the quantity of neomycin that would be present when the sample is diluted to contain 100 units of polymyxin B (labeled potency) per milliliter. Prepare the polymyxin standard curve by adding this calculated quantity of neomycin to each concentration of polymyxin used for the curve. Use this standard curve to calculate the polymyxin content of the sample.

(ii) If the sample contains sodium ethylmercurithiosalicylate, incorporate 0.03 percent thioglycolic acid in the seed layer just before preparing the plates.

(iii) Its content of polymyxin B is satisfactory if it contains not less than 85 percent of the number of units per milliliter that it is represented to contain.

(b) *Moisture (dry components of the drug).* Proceed as directed in § 141a.5 (a) of this chapter.

§ 141e.425 *Bacitracin powder*—(a) *Potency.* Proceed as directed in § 141e.401 (a) (1), except in lieu of the directions for preparing the sample in § 141e.401 (a) (1) (ii), prepare the sample as follows: Place an accurately weighed sample of approximately 1 to 5 grams in a 100-milliliter volumetric flask, dissolve in water, and dilute to 100 milliliters with water. Dilute a suitable aliquot with 1-percent phosphate buffer to a concentration of 1 unit per milliliter (estimated). Its potency is satisfactory if it contains not less than 85 percent of the number of units of bacitracin per pound that it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

§ 141e.426 *Tablets bacitracin methylene disalicylate and streptomycin sulfate oral veterinary*—(a) *Potency*—(1) *Bacitracin content.* Use 6 finely powdered tablets and proceed as directed in § 141e.417 (a) (1). Its bacitracin activity is satisfactory if it is not less than 85 percent of that which it is represented to contain.

(2) *Streptomycin content.* Proceed as directed in § 141b.109 (a) (1) of this chapter. Its streptomycin activity is satisfactory if it is not less than 85 percent of that which it is represented to contain.

(b) *Moisture.* Proceed as directed in § 141a.5 (a) of this chapter.

PART 146—GENERAL REGULATIONS FOR THE CERTIFICATION OF ANTIBIOTIC AND ANTIBIOTIC-CONTAINING DRUGS

Sec.
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146.24 Penicillin for diagnostic use; streptomycin for diagnostic use; dihydrostreptomycin for diagnostic use; chlortetracycline for diagnostic use; tetracycline for diagnostic use; chloramphenicol for diagnostic use; bacitracin for diagnostic use.
146.25 Penicillin for use in animal feed; streptomycin for use in animal feed; dihydrostreptomycin for use in animal feed; chlortetracycline for use in animal feed; chloramphenicol for use in animal feed; bacitracin for use in animal feed; bacitracin methylene disalicylate for use in animal feed.
146.26 Animal feed containing penicillin; animal feed containing streptomycin; animal feed containing dihydrostreptomycin; animal feed containing chlortetracycline; animal feed containing tetracycline; animal feed containing chloramphenicol; animal feed containing bacitracin; animal feed containing bacitracin methylene disalicylate.
146.27 Antibiotics for fish diseases.
146.28 Antibiotics for bull semen.
146.29 Biological drugs that contain antibiotics.

AUTHORITY: §§ 146.1 to 146.29 issued under sec. 701, 52 Stat. 1055; 21 U. S. C. 371. Interpret or apply sec. 507, 59 Stat. 463, as amended; 21 U. S. C. 357.

§ 146.1 *Definitions and interpretations.* For the purpose of the regulations in this part:

(a) Each of the several antibiotic substances (e. g. penicillin F, penicillin G, penicillin X) produced by the growth of Penicillium notatum or Penicillium chrysogenum, and each of the same substances produced by any other means, is a kind of penicillin.

(b) Each of the several antibiotic substances produced by the growth of Streptomyces griseus, and each of the same substances produced by any other means, is a kind of streptomycin.

(b-1) Each of the antibiotic substances produced by hydrogenation of streptomycin and each of the same substances produced by any other means is a kind of dihydrostreptomycin.

(c) Each of the several antibiotic substances produced by the growth of Streptomyces aureofaciens, and each of the same substances produced by any other means, is a kind of chlortetracycline.

(c-1) Each of the several antibiotic substances produced by the hydrogenation of chlortetracycline and each of the same substances produced by any other means is a kind of tetracycline.

(d) Each of the several antibiotic substances produced by the growth of Streplus subtilis var. Tracy, and each of the same substances produced by any other means, is a kind of chloramphenicol.

(e) Each of the several antibiotic substances produced by the growth of Bacillus subtilis var. Tracy, and each of the same substances produced by any other means, is a kind of bacitracin.

(f) The term "penicillin G master standard" means a specific lot of crystalline sodium penicillin G (sodium penicillin II), which is designated by the Commissioner as the standard of comparison in determining the potency of the penicillin G working standards. The term "penicillin O master standard" means a specific lot of crystalline potassium penicillin O standardized by the penicillin G master standard and which is designated by the Commissioner as the standard of comparison in determining the penicillin O content of the penicillin O working standard. The term "penicillin V master standard" means a specific lot of crystalline penicillin V which is designated by the Commissioner as the standard of comparison in determining the potency of the penicillin V working standard.

(g) The term "streptomycin master standard" means a specific lot of crystalline trihydrochloride calcium chloride salt of streptomycin which is designated by the Commissioner as the standard of comparison in determining the potency of the streptomycin working standard.

(h) The term "dihydrostreptomycin master standard" means a specific lot of crystalline dihydrostreptomycin sulfate which is designated by the Commissioner as the standard of comparison in determining the potency of the dihydrostreptomycin working standard.

(i) The term "chlortetracycline master standard" means a specific lot of crystalline chlortetracycline hydrochloride which is designated by the Commissioner as the standard of comparison in determining the potency of the chlortetracycline working standard.

(i-1) The term "tetracycline master standard" means a specific lot of crystalline tetracycline hydrochloride which is designated by the Commissioner as the standard of comparison in determining the potency of the tetracycline working standard.

(j) The term "chloramphenicol master standard" means a specific lot of crystalline chloramphenicol which is designated by the Commissioner as the standard of comparison in determining the potency of the chloramphenicol working standard.

(k) The term "bacitracin master standard" means a specific lot of bacitracin which is designated by the Commissioner as the standard of comparison in determining the potency of the bacitracin working standard.

(l) The term "unit" applied to penicillin means a penicillin activity contained in 0.6 microgram of the penicillin G master standard, except the term "unit" applied to penicillin V means a penicillin activity contained in 0.59 microgram of the penicillin V master standard; the term "penicillin potency" means the number of such units in a specified quantity of a substance. The term "unit" applied to bacitracin means a bacitracin activity contained in 23.8 migrograms of the bacitracin master standard after it is dried for 3 hours at 60° C. and a pressure of 5 millimeters or less; the term "bacitracin potency" means the number of such units in a specified quantity of a substance.

(m) The term "microgram" applied to streptomycin means the streptomycin activity (potency) contained in 1.38 micrograms of the streptomycin master standard after it is dried for 4 hours at 56° C. and a pressure of 50 microns or less. The term "microgram" applied to dihydrostreptomycin means the dihydrostreptomycin activity (potency) contained in 1.25 micrograms of the dihydrostreptomycin master standard after it is dried for 4 hours at 100° C. and a pressure of 50 microns or less. The term "microgram" applied to chlortetracycline means the chlortetracycline activity (potency) contained in 1.0 microgram of the chlortetracycline master standard. The term "microgram" applied to tetracycline means the tetracycline activity (potency) contained in 1.0 microgram of the tetracycline master standard. The term "microgram" applied to chloramphenicol means the chloramphenicol activity (potency) contained in 1.0 microgram of the chloramphenicol master standard.

(n) The term "penicillin G working standard" means a specific lot of a homogeneous preparation of one or more salts of penicillin G; the term "penicillin O working standard" means a specific lot of a homogeneous preparation of potassium penicillin O; the term "penicillin V working standard" means a specific lot of a homogeneous preparation of penicillin V; the term "streptomycin working standard" means a specific lot of a homogeneous preparation of one or more streptomycin salts; the term "dihydrostreptomycin working standard" means a specific lot of a homogeneous preparation of one or more dihydrostreptomycin salts; the term "chlortetracycline working standard" means a specific lot of a homogeneous preparation of one or more chlortetracycline salts; the term "tetracycline working standard" means a specific lot of a homogeneous preparation of one or more tetracycline salts; the term "chloramphenicol working standard" means a specific lot of a homogeneous preparation of one or more chloramphenicols; the term "bactracin working standard" means a specific lot of a homogeneous preparation of one or more bacitracins. The potency or purity of each preparation has been deterbined by comparison with its master standard, and each has been designated by the Commissioner as working standards for use in determining the potency or purity of drugs subject to the regulations in this part.

(o) The term "batch" means a specific homogeneous quantity of a drug.

(p) The term "batch mark" means an identifying mark or other identifying device assigned to a batch by the manufacturer or packer thereof.

(q) The term "Commissioner" means the Commissioner of Food and Drugs and any other officer of the Food and Drug Administration whom he may designate to act in his behalf for the purposes of the regulations in this part.

(r) The term "U. S. P." means the official Pharmacopeia of the United States, including supplements thereto. The term "N. F." means the official National Formulary, including supplements thereto.

(s) The term "manufacture" does not include the use of a drug as an ingredient in compounding any prescription issued by a practitioner licensed by law to administer such drug.

(t) All statements, samples, and other information and materials submitted in connection with a request for certification shall be considered to be a part of such request.

(u) The definitions and interpretations of terms contained in section 201 of the Federal Food, Drug, and Cosmetic Act shall be applicable to such terms when used in the regulations in this part.

(v) Except as specifically provided by §§ 146.8 to 146.23, inclusive, no provision of any section in this part shall be construed as exempting any drug from any applicable provision of the act or other regulation thereunder.

(w) The regulations in Parts 141a, 141b, 141c, 141d, and 141e of this chapter prescribing tests and methods of assays shall not be construed as preventing the Commissioner from using any other test or method of assay in his investigations to determine whether or not:

(1) A request for certification contains any untrue statement of a material fact; or

(2) A certification has been obtained through fraud, or through misrepresentation or concealment of a material fact.

(x) Wherever the potency of an antibiotic drug included in the regulations in this chapter is expressed in terms of weight, such potency shall be equivalent to that contained in the same weight of the master standard of the drug.

§ 146.2 *Requests for working standards and certification; information and samples required.* (a) A request for certification of a batch shall be addressed to the Commissioner and shall be in a form specified by him. A request from a foreign manufacturer shall be signed by such manufacturer and by an agent of such manufacturer who resides in the United States.

(b) The initial request for certification of a batch of any drug submitted by any person shall be preceded or accompanied by a full statement of the facilities and controls used to maintain the identity, strength, quality, and purity of each batch, including a description of (1) the methods and processes used in the manufacture of the drug; (2) the tests and assays of the drug made during the manufacture of the batch and after it is packaged; and (3) the laboratory facilities used in such controls. Such initial request shall also be preceded or accompanied by the key of the batch marks used by such person and by specimens of all labeling (including specimens of all brochures and other printed matter except readily available medical publications, referred to in such labeling) to be used for such drug. When any change is made in any such facility or control, or in any such key or labeling, such person shall promptly submit to the Commissioner a full statement of such change or, in the case of changed labeling, specimens showing all such changes.

(c) Each sample submitted pursuant to the regulations in this part shall be addressed to the Commissioner. Its package shall be clearly identified as to its contents and shall bear the name and post-office address of the person submitting it.

(d) In addition to the information and samples specifically required to be submitted to the Commissioner by the regulations in this part, the person who requests certification of a batch shall submit such further information and samples as the Commissioner may require for the purpose of investigations to determine whether or not such batch complies with the requirements of § 146.3 for the issuance of a certificate.

(e) Upon the request of any person, stating reasonable grounds therefor, the Commissioner shall furnish such person with a portion of the working standards.

§ 146.3 *Certification.* (a) If it appears to the Commissioner, after such investigation as he considers necessary, that:

(1) The information (including results of tests and assays) and samples required by or pursuant to the regulations in this part have been submitted, and the request for certification contains no untrue statement of a material fact; and

(2) The batch complies with the regulations in this part and conforms to the applicable standards of identity, strength, quality, and purity prescribed by the regulations in this part;

the Commissioner shall certify that such batch is safe and efficacious for use, subject to such conditions on the effectiveness of certificates as are prescribed by § 146.4, and shall issue to the person who requested it a certificate to that effect.

(b) If the Commissioner determines, after such investigation as he considers to be necessary, that the information submitted pursuant to the regulations in this part, or the batch covered by such request, does not comply with the requirements set forth in paragraph (a) of this section for the issuance of a certificate, the Commissioner shall refuse to certify such batch and shall give notice thereof to the person who requested certification, stating his reasons for refusal.

(c) Compliance of a drug with the standards of identity, strength, quality, and purity prescribed by regulations in this part shall be determined by the tests and methods of assay prescribed for such drug by regulations in Parts 141a to 141e of this chapter.

§ 146.4 *Conditions on the effectiveness of certificates.* (a) A certificate shall not become effective:

(1) If it is obtained through fraud or through misrepresentation or concealment of a material fact;

(2) With respect to any package unless it complies with the packaging requirements, if any, prescribed by the regulations in this part which were in effect on the date of the certificate;

(3) With respect to any package unless its label and labeling bear all words, statements, and other information required by the regulations in this part; or

(4) With respect to any package of penicillin, streptomycin, dihydrostreptomycin, chlortetracycline, chloramphenicol, or bacitracin, when it is included in a packaged combination with another drug, unless such other drug complies with the requirements of the regulations in this part.

(b) A certificate shall cease to be effective:

(1) With respect to any immediate container after the expiration date, if any, prescribed by the regulations in this part;

(2) With respect to any immediate container when it or its seal (if the regulations in this part require it to be sealed) is broken, or when its label or labeling is altered, mutilated, destroyed, obliterated, or removed in whole or in part, or ceases to conform to any labeling requirement prescribed by the regulations in this part, except that:

(i) If the drug in such container is repacked or used as an ingredient in the manufacture of another drug, and certification of the batch thus made is requested, such certificate shall continue to be effective for a reasonable time to permit certification or destruction of such batch;

(ii) If the drug is in a container packaged for dispensing and is used in compounding a prescription issued by a practitioner licensed by law to administer such drug, such certificate shall continue to be effective for a reasonable time to permit the delivery of the drug compounded on such prescription; or

(iii) If its label or labeling is removed in whole or in part for the purpose of relabeling and supplemental certification of the relabeled drug is requested, as provided by § 146.18.

(3) With respect to any immediate container of penicillin when it is included in the packaged combination penicillin with aluminum hydroxide gel or penicillin with a vasoconstrictor, or to any immediate container of bacitracin when it is included in the packaged combination bacitracin with a vasoconstrictor, except that when certification of the batch so included is requested, such certificate shall continue to be effective for a reasonable time to permit certification of such batch which is part of such combination;

(4) With respect to any package when the drug therein fails to meet the standards of identity, strength, quality, and purity which were in effect on the date of the certificate; except that those minor changes which occur before the expiration date and which are normal and unavoidable in good storage and distribution practice shall be disregarded;

(5) With respect to any package of penicillin, streptomycin, dihydrostreptomycin, chlortetracycline, chloramphenicol, or bacitracin, included in a packaged combination with another drug, when such other drug fails to meet the requirements of the regulations in this part; or

(6) With respect to any immediate container, if such regulations require its labeling to bear a caution against dispensing otherwise than on prescription, at the beginning of the act of dispensing or offering to dispense it otherwise than:

(i) By a practitioner licensed by law to administer such drug; or

(ii) On his prescription issued in his professional practice.

§ 146.5 *Records of distribution.* (a) The person who requested certification shall keep complete records showing each shipment and other delivery (including exports) of each certified batch or part thereof by such person or by any person subject to his control. Such records shall show the date and quantity of each such shipment or delivery and the name and post-office address of the person to whom such shipment or delivery was made, and shall be kept for not less than three years after such date.

(b) Upon the request of any officer or employee of the Food and Drug Administration, or of any other officer or employee of the United States acting on behalf of the Secretary, the person to whom a certificate is issued shall at all reasonable hours make such records available to any such officer or employee and shall accord to him full opportunity to make inventory of stocks of such batch on hand and otherwise to check the correctness of such records.

§ 146.6 *Authority to refuse certification service.* When the Secretary finds, after giving notice and opportunity for hearing, that a person has:

(a) Obtained or attempted to obtain a certificate through fraud, or through misrepresentation or concealment of a material fact;

(b) Falsified the records required to be kept by § 146.5; or

(c) Failed to keep such records or to make them available, or to accord full opportunity to make an inventory of stocks on hand or otherwise to check the correctness of such records, as required by § 146.5, and such failure may materially impair the certification service;

the Secretary will immediately suspend service to such person under the regulations in this part and will continue such suspension unless and until such person shows adequate cause why such service should be resumed.

§ 146.7 *New antibiotic and antibiotic-containing products.* Any request that the Secretary provide for the certification of batches of a drug for which no provision for certification is made in the existing regulations in this part shall be in a form specified by the Commissioner and shall be accompanied by:

(a) A statement of the conditions for which the person who makes such request intends such drug to be used, and adequate directions for use in each such condition;

(b) Full reports of investigations which have been made to show whether or not such drug is safe and efficacious for use in such conditions;

(c) A full list of the articles used as components of such drug;

(d) A full statement of the composition of such drug;

(e) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

(f) A full description of, or references to publications containing practical and accurate tests and methods of assay to determine the identity, strength, quality, and purity of such drug;

(g) Such samples of such drug and of the articles used as components thereof as the Commissioner may require; and

(h) Specimens of all labeling (including all brochures and other printed matter, except readily available medical publications, referred to in such labeling) proposed to be used for such drug.

§ 146.8 *Fees.* (a) Fees for the services rendered under the regulations in this part shall be such as are necessary to provide, equip, and maintain an adequate certification service.

(b) The fee for such services with respect to each batch of a drug, certification of which is provided by the regulations in this part, is the fee prescribed in the section relating specifically to such drug, except that, in case of a supplemental request submitted pursuant to the provisions of § 146.18, the fee shall be $2.00.

(c) When the Commissioner considers it necessary to make investigations of a new penicillin, streptomycin, dihydrostreptomycin, chlortetracycline, chloramphenicol, or bacitracin product, on which a request has been submited in accordance with § 146.7, the fee for such service shall be the cost thereof. In such case the request shall be followed by an advance deposit in such amount as the Commissioner specifies, and thereafter such additional advance deposits shall be made as the Commissioner estimates may be necessary to prevent arrears in the payment of such fee.

(d) A person requiring continuing certification services may maintain an advance deposit of the estimated cost of such services for a two-month period. Such deposit shall be debited with fees for services rendered, but shall not be debited for any fee the amount of which is not definitely specified in the regulations in this part unless the depositor has previously requested the performance of the services to be covered by such fee. A monthly statement for each such advance deposit shall be rendered.

(e) The unearned portion of any advance deposit shall be refunded to the depositor upon his application.

(f) Whenever in the judgment of the Commissioner the ratio between fees collected (which are based upon experience and the best estimate of costs and the best estimate of earnings) and the costs of providing the service during an elapsed period of time, in the light of all circumstances and contingencies, warrants a refund from the fund collected during such period, he shall make ratable refunds to those persons to whom the services were rendered and charged, except for those services described under § 146.18.

(g) All deposits and fees required by the regulations in this part shall be paid by money order, bank draft, or certified check drawn to the order of the Treasurer of the United States, collectible at par at Washington, D. C. All such deposits and fees shall be forwarded to the Food and Drug Administration, Department of Health, Education, and Welfare, Washington 25, D. C., whereupon after making appropriate records thereof they will be transmitted to the Chief Disbursing Officer, Division of Disbursement, Treasury Department, for deposit to the special account "Certification and Inspection Services, Food and Drug Administration."

§ 146.9 *Antibiotics for agricultural use.* An article that contains one or more of the antibiotic substances described in this part and intended solely for application to plants for the control of plant diseases caused by microorganisms and conspicuously so labeled is not subject to the requirements of sections 502 (l) and 507 of the Federal Food, Drug, and Cosmetic Act, if it contains one or more suitable denaturants that make it unfit for drug use; but in no case shall it be exempt from the requirements of sections 502 (l) and 507 of the act if it is represented or intended to be administered to man or other animals for the cure, mitigation, treatment, or prevention of disease or as an animal feed supplement.

§ 146.10 *Antibiotics for export.* Drugs containing penicillin, streptomycin, dihydrostreptomycin, chlortetracycline, tetracycline, chloramphenicol, or bacitracin intended for export will be certified notwithstanding failure to meet the labeling requirements of the applicable monographs if the labeling used for such drugs complies with the following conditions:

(a) It has been approved before use by the government authorities of the country to which the drugs are intended for export; and

(b) Such labeling represents that such drugs are for use only in those conditions for which they are certified for domestic distribution.

§ 146.18 *Exemptions for labeling.* (a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of a drug which is to be labeled at an establishment located elsewhere than at the place of manufacture shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment, from the requirements of section 502 (l) of the act if the labeling of each shipping container bears the batch mark of the drug, the number of units per package, the expiration date, and if the person who introduced such shipment or delivery into interstate commerce holds a permit from the Commissioner authorizing shipment for labeling in such establishment.

(b) (1) An application for such a permit shall be in a form specified by the Commissioner, and shall give the name and location of the establishment in which such labeling is to be done.

(2) In case the applicant is the operator of such establishment, the application shall include a written agreement signed by him that he will request certification of each batch from which any shipment or delivery is made to such establishment unless it is exempt under section 801 (d) of the act or § 146.23; that he will not remove any of such drug from such establishment unless it complies with section 502 (l) of the act or is so exempt, or if certification is refused, unless it is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured; that he will keep complete records showing the date, quantity, and batch mark of each such shipment and delivery and the disposition thereof; that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such disposition; and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records.

(3) In case the applicant is not the operator of such establishment such application shall include or be accompanied by:

(i) A written agreement signed by the applicant that he will request certification of each batch from which any shipment or delivery is made to such establishment unless it is exempt under section 801 (d) of the act or § 146.23; that he will keep complete records showing the date, quantity, and batch mark of each such shipment and delivery; and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such shipment or delivery; and

(ii) A written agreement signed by the operator of such establishment that he will submit a request, supplemental to that of the applicant, for the certification of each batch or portion thereof comprised in any such shipment or delivery received by him unless it is exempt under section 801 (d) of the act or § 146.23; that he will specify in his request the number of packages of each size in such shipment or delivery, the date of delivery, the batch mark thereof, and the batch mark he will use therefor; that the batch marks to be used (if different from those of the applicant) will be only those of which the key is specified in this agreement that the expiration date used for the batch will be only that assigned to the manufacturer by certification; that the labeling to be used for such packages will be only that of which specimens are attached to this agreement (including specimens of all brochures and other printed matter, except readily available medical publications, referred to in such labeling); that when any change is made in such key or labeling he will promptly submit to the Commissioner a full statement of such change or, in the case of changed labeling, specimens showing all such changes; that he will not remove any of such drug from such establishment unless it complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or § 146.23 or, if certification is refused, unless it is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured; that he will keep complete records of the disposition of each such shipment and delivery; that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such disposition; and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records.

(4) When the Commissioner finds, after giving notice and opportunity for hearing, that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such establishment, shall become void at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after labeling, from such establishment unless such batch complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or § 146.23 or, if certification is refused, unless such shipment or delivery is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

(d) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is not the operator of such establishment, shall expire at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after labeling, from such establishment unless such batch complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or § 146.23 or, if certification is refused, unless such shipment or delivery, within a reasonable time, is destroyed or returned to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

§ 146.19 *Exemptions for storage.* (a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of a drug which is to be stored at a warehouse located elsewhere than at the place of manufacture shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such warehouse, from the requirements of section 502 (l) of the act if the labeling of each shipping container bears the batch mark of the drug, and if the person who introduced such shipment or delivery into interstate commerce holds a permit from the Commissioner authorizing shipment for storage in such warehouse.

(b) An application for such a permit shall be in a form specified by the Commissioner, and shall give the name and location of the warehouse in which such drug is to be stored. Such application shall be accompanied by:

(1) A written agreement signed by the applicant that he will request certification of each batch thereof unless it is exempt under section 801 (d) of the act or §§ 146.18, 146.21, or 146.22, that he will not remove any of such drug from such warehouse unless it complies with section 502 (l) of the act or is so exempt or, if certification is refused unless it is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured; that he will keep complete records showing the date, quantity, and batch mark of each shipment and other delivery of any such drug to such warehouse, and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such shipment or delivery; and

(2) A written statement signed by the operator of such warehouse showing that he has adequate facilities for such storage; such statement shall contain an agreement that he will hold each shipment or other delivery of such drug intact, under such conditions as will not cause failure of the drug to comply with the requirements for certification, that he will keep complete records showing the date of receipt by him and the quantity and batch mark of each such shipment and delivery and the disposition thereof, that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such disposition, and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records.

If the applicant keeps complete records showing the date, quantity, and batch mark of each shipment and other delivery of any such drug from such warehouse and the name and post-office address of the person to whom such shipment or delivery was made, the agreement to keep records of such disposals, to make such records available, and to afford opportunity for checking their correctness may be included in the applicant's agreement and omitted from that of the operator. When the Commissioner finds, after giving notice and opportunity for hearing, that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such warehouse, shall become void at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof from such warehouse unless such batch complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or §§ 146.18, 146.21, or 146.22, or, if certification is refused, unless such shipment or delivery is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

(d) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is not the operator of such warehouse, shall expire at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof from such warehouse unless such batch complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or §§ 146.18, 146.21, or 146.22, or, if certification is refused, unless such shipment or delivery, within a reasonable time, is destroyed, or returned to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

§ 146.20 *Exemptions for processing.* (a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of penicillin, streptomycin, dihydrostreptomycin, chlortetracycline, chloramphenicol, or bacitracin in concentrated aqueous solution which is to be processed at an establishment located elsewhere than at the place of manufacture shall be exempt during the time of introduction into and movement in interstate commerce and the time of holding in such establishment from the requirements of section 502 (l) of the act, if the person who introduced such shipment or delivery into interstate commerce holds a permit from the Commissioner authorizing shipment for processing in such establishment, and each package of such solution bears the batch mark of the drug.

(b) An application for such a permit shall be in a form specified by the Commissioner and shall give the name and location of the establishment in which such processing is to be done. Such application shall be accompanied by:

(1) A written agreement signed by the applicant that he will keep complete records showing the date, quantity, potency, and batch mark of each shipment and other delivery of any such solution to such establishment, and that he will make such records available to any offi-

cer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such shipment or delivery;

(3) A written agreement signed by the operator of such establishment showing that he has adequate facilities for such processing; such statement shall contain an agreement that he will keep complete records showing the date of receipt by him and the quantity and batch mark of each such shipment and delivery and the disposition thereof, that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after date of such disposition, and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records; and

(3) A written agreement signed by the person who will own the drug after the processing is completed that he will request certification of each batch thereof unless it is exempt under section 801 (d) of the act or §§ 146.18, 146.19, 146.21, 146.22, or 146.23, and that he will not remove any of such drug from such establishment unless it complies with section 502 (l) of the act or is so exempt.

When the Commissioner finds, after giving notice and opportunity for hearing, that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such establishment, shall become void at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after processing, from such establishment unless the batch made from such shipment or delivery complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or §§ 146.18, 146.19, 146.21, 146.22, or 146.23 or, if certification is refused, unless such shipment or delivery is reprocessed and certified or destroyed within a reasonable time.

(d) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is not the operator of such establishment, shall expire at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after processing, from such establishment unless the batch made from such shipment or delivery complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or §§ 146.18, 146.19, 146.21, 146.22, or 146.23, or, if certification has been refused, unless such shipment or delivery is reprocessed and certified or destroyed within a reasonable time.

§ 146.21 *Exemptions for repacking.* (a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of a drug which is to be repacked at an establishment located elsewhere than at the place of manufacture shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in such establishment from the requirements of section 502 (l) of the act if the labeling of each container bears the batch mark of the drug and the number of units per package, and if the person who introduces such shipment or delivery into interstate commerce holds a permit from the Commissioner authorizing shipment for repacking in such establishment.

(b) An application for such a permit shall be in a form specified by the Commissioner, and shall give the name and location of the establishment in which such repacking is to be done. Such application shall be accompanied by:

(1) A written agreement signed by the applicant that he will keep complete records showing the date, quantity, and batch mark of each shipment and other delivery of any such drug to such establishment, and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of each shipment or delivery;

(2) A written statement signed by the operator of such establishment showing that he has adequate facilities for such repacking; such statement shall contain an agreement that he will keep complete records showing the date of receipt by him and the quantity and batch mark of each such shipment and delivery and the disposition thereof, that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such disposition, and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records; and

(3) A written agreement signed by the person who will own the drug after the repacking is completed that he will request certification of each batch thereof unless it is exempt under section 801 (d) of the act or §§ 146.18, 146.19, or 146.23, and that he will not remove any of such drug from such establishment unless it complies with section 502 (l) of the act or is so exempt or is returned to him for labeling or, if certification is refused, unless it is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

When the Commissioner finds, after giving notice and opportunity for hearing, that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such establishment, shall become void at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after repacking, from such establishment unless such batch complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or §§ 146.18, 146.19, or 146.23 or is returned to such person for labeling or, if certification is refused, unless such shipment or delivery is returned within a reasonable time to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

(d) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is not the operator of such establishment, shall expire at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof, before or after repacking, from such establishment unless such batch complies with section 502 (l) of the act or is exempt under section 801 (d) of the act or §§ 146.18, 146.19, or 146.23 or is returned to such person for labeling or, if certification is refused, unless such shipment or delivery, within a reasonable time, is destroyed or returned to permit reprocessing and certification, destruction, or such exemption at the establishment where it was manufactured.

§ 146.22 *Exemptions for manufacturing use.* (a) Except as provided by paragraphs (c) and (d) of this section, a shipment or other delivery of penicillin, streptomycin, dihydrostreptomycin, chlortetracycline, chloramphenicol, or bacitracin which is packed in containers of not less than 10,000,000 units of penicillin or 10 grams of streptomycin, dihydrostreptomycin, chlortetracycline, chloramphenicol, or bacitracin each shall be exempt, during the time of introduction into and movement in interstate commerce and the time of holding in the establishment where it is so used, from the requirements of section 502 (l) of the act, if it conforms to the standards prescribed therefor by the section of the regulations in this part which is specifically applicable to such other drug, if the label of each container bears the batch mark of the drug, the number of units or grams per package, and the date on which the latest assay of the drug was completed, and if the person who introduced each shipment or delivery into interstate commerce holds a permit from the Commissioner authorizing shipment for manufacturing use in such establishment.

(b) An application for such a permit shall be in a form specified by the Commissioner, shall give the name and location of the establishment in which such drug is to be used and shall be accompanied by:

(1) A written agreement signed by the applicant that he will keep complete records showing the date, quantity, and batch mark of each shipment and other delivery of any such drug to such establishment, and that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three

years after the date of such shipments or delivery;

(2) A written statement signed by the operator of such establishment showing that he has adequate facilities for the manufacture of such other drug; such statement shall contain an agreement that he will keep complete records showing the date of receipt by him and the quantity and batch mark of each such shipment and delivery and the disposition thereof and showing the quantity and batch mark of each batch of such other drug manufactured by him and the disposition thereof; that he will make such records available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such disposition, and that he will accord full opportunity to such officer or employee to make inventories of stocks on hand and otherwise check the correctness of such records; and

(3) A written agreement signed by the person who will own the drug after its manufacture is completed that he will request certification of each batch thereof unless it is exempt under section 801 (d) of the act or §§ 146.18, 146.19, 146.21, or 146.23, and that he will not remove any of such drug from such establishment unless it complies with section 502 (l) of the act or is so exempt or is returned to him for labeling.

When the Commissioner finds, after giving notice and opportunity for hearing, that such application contains any untrue statement of a material fact or that any provision of any such agreement has been violated he may revoke such permit.

(c) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is the operator of such establishment, shall become void at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof from such establishment, prior to its use in the manufacture of another drug, unless it is exempt under section 801 (d) of the act.

(d) An exemption of a shipment or other delivery under paragraph (a) of this section, in case the person who introduced such shipment or delivery into interstate commerce is not the operator of such establishment, shall expire at the beginning of the act of removing or offering to remove such shipment or delivery or any part thereof from such establishment, prior to its use in the manufacture of another drug, unless it is exempt under section 801 (d) of the act.

§ 146.23 *Exemptions for investigational use.* (a) A shipment or other delivery of a drug shall be exempt from section 502 (l) of the act if all of the following requirements are complied with:

(1) The label of such drug bears the batch mark and the statement "Caution: Limited by Federal law to investigational use only."

(2) Such shipment or delivery is made only to, and solely for investigational use by or under the direction of, an expert qualified by scientific training and experience to investigate the safety or efficacy of such drug.

(3) The person who introduced such shipment or delivery into interstate commerce keeps complete records showing the date, quantity, and batch mark of each such shipment and delivery.

(4) Such person, prior to making such shipment or delivery, obtains a statement signed by such expert showing that he has adequate facilities for the investigation to be conducted by him, and that such drug will be used solely by him or under his direction for the investigation. Such person shall keep such statement. This subparagraph shall not apply when such shipment or delivery is made to an agency of the Government of the United States (including the National Research Council) or to any State or municipality whose official functions involve investigations of such drugs by such experts.

(5) Such person makes all documents referred to in subparagraphs (3) and (4) of this paragraph available to any officer or employee of the Food and Drug Administration at any reasonable hour within three years after the date of such shipment or delivery.

(b) A shipment or other delivery of a drug which is being imported or offered for import into the United States shall be exempt from section 502 (l) of the act if all the following requirements are complied with:

(1) The label of such drug bears the batch mark and the statement "Caution: Limited by Federal law to investigational use only."

(2) The importer of such shipments or deliveries is an agent of the foreign exporter, residing in the United States, or the operator of an establishment in the United States which has facilities for regularly investigating the safety or efficacy of such drugs, which facilities are manned by experts qualified by scientific training and experience to conduct such investigation.

(3) Such operator uses such drug solely for such investigation in such establishment, or such operator or agent otherwise disposes of such drug only to, and solely for, investigational use by or under the direction of such an expert other than one in such an establishment.

(4) Such importer, prior to disposing of any of such drug to such an expert, obtains a statement signed by such expert showing that he has adequate facilities for the investigation to be conducted by him, and that such drug will be used solely by him or under his direction for the investigation. Such importer shall keep such statement. This subparagraph shall not apply to any shipment or delivery or part thereof disposed of by such importer to an agency of the Government of the United States (including the National Research Council) or to any State or municipality whose official functions involve investigations of such drugs by such experts.

(5) Such importer who introduced such shipment or delivery into interstate commerce keeps complete records showing the date, quantity, and batch mark of each such shipment and delivery.

(6) Such importer makes all documents referred to in subparagraphs (4) and (5) of this paragraph available to any officer or employee of the Food and Drug Administration at any reasonable hour within 3 years after the date of such shipment or delivery by such importer.

(c) An exemption under paragraph (a) or (b) of this section shall become void ab initio if any record or statement required by such paragraph to be kept and made available for inspection is not kept or made available as so required.

(d) An exemption under paragraph (a) or (b) of this section shall expire with respect to any exempted shipment or delivery or part thereof which has been supplied to an expert who has signed the statement referred to in paragraph (a) (4) or (b) (4) of this section and which is used otherwise than in accordance with such signed statement.

(e) An exemption under paragraph (b) of this section shall become void ab initio if the exempted shipment or delivery or any part thereof is disposed of otherwise than as provided by subparagraph (3) of such paragraph.

(f) No exemption under paragraph (b) of this section shall apply to any shipment or delivery to such importer if such importer, within 3 years prior to the offering of such shipment or delivery for import, has caused an exemption to become void as provided by paragraph (c) or (e) of this section.

§ 146.24 *Penicillin for diagnostic use; streptomycin for diagnostic use; dihydrostreptomycin for diagnostic use; chlortetracycline for diagnostic use; tetracycline for diagnostic use; chloramphenicol for diagnostic use; bacitracin for diagnostic use.* (a) Penicillin, streptomycin, dihydrostreptomycin, chlortetracycline, tetracycline, chloramphenicol, or bacitracin, packaged for dispensing and intended for use solely in laboratory procedures in connection with the diagnosis or treatment of disease and conspicuously so labeled, shall be exempt from the requirements of sections 502 (l) and 507 of the act if each package bears on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The statement "Not for therapeutic use. For use in laboratory diagnosis only."

(ii) The potency of each such tablet, disc, vial, or other such form.

(iii) The batch mark.

(iv) The statement "Expiration date ----------," the blank being filled in with the date which is not more than 24 months after the month during which the batch was last assayed and released by the manufacturer: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the circular or other labeling within or attached to the package, directions adequate for the use of such drug.

§ 146.25 *Penicillin for use in animal feed; streptomycin for use in animal feed; dihydrostreptomycin for use in animal feed; chlortetracycline for use in* *animal feed; chloramphenicol for use in animal feed; bacitracin for use in animal feed; bacitracin methylene disalicylate for use in animal feed.* Penicillin, streptomycin, dihydrostreptomycin, chlortetracycline, chloramphenicol, bacitracin or bacitracin methylene disalicylate, or any combination of two or more of these, with or without those ingredients specified in § 146.26, intended for use solely as an ingredient in the manufacture of animal feed and conspicuously so labeled shall be exempt from the requirements of sections 502 (l) and 507 of the act if it complies with the following conditions:

(a) It contains one or more suitable denaturants that make it unfit for human use; and

(b) Its labeling is such that animal feed mixed according to the directions contained therein complies with the requirements of § 146.26.

§ 146.26 *Animal feed containing penicillin; animal feed containing streptomycin; animal feed containing dihydrostreptomycin; animal feed containing chlortetracycline; animal feed containing tetracycline; animal feed containing chloramphenicol; animal feed containing bacitracin; animal feed containing bacitracin methylene disalicylate.* Animal feed containing penicillin, streptomycin, dihydrostreptomycin, chlortetracycline, tetracycline, chloramphenicol, bacitracin, or bacitracin methylene disalicylate, or any combination of two or more of these, with or without added suitable vitamin substances, shall be exempt from the requirements of sections 502 (l) and 507 of the act under the conditions set forth in any one of the following paragraphs of this section:

(a) It is intended for use solely as an animal feeding supplement, it is conspicuously so labeled, and it is manufactured with or without one, but only one, of the following ingredients in a quantity, by weight of feed, as hereinafter indicated:

(1) Arsanilic acid: Not less than 0.005 percent and not more than 0.01 percent.

(2) Sodium arsanilate: Not less than 0.005 percent and not more than 0.01 percent.

(3) 3-Nitro-4-hydroxyphenol arsonic acid: Not less than 0.0025 percent and not more than 0.0075 percent.

(b) It is intended for use in the conditions set forth in any one of the following subparagraps of this paragraph:

(1) It is intended for use solely in the prevention of coccidiosis outbreaks in poultry flocks, its labeling bears adequate directions and warnings for such use, and it contains one, but only one, of the following ingredients in a quantity, by weight of feed, as hereinafter indicated:

(i) Sulfaquinoxaline: Not less than 0.0125 percent (or if it is intended solely for the prevention of the intestinal coccidia *E. acervalina* in poultry laying flocks, not less than 0.005 percent) and not more than 0.025 percent.

(ii) Nitrophenide: Not less than 0.0125 percent and not more than 0.025 percent.

(iii) Nitrofurazone: 0.0056 percent.

(iv) N^4-acetyl-N^1-(4-nitrophenyl) sulfanilamide 0.03 percent and 3-nitro-4-hydroxyphenylarsonic acid 0.009 percent.

(2) It is intended for use solely in the control of coccidiosis outbreaks in poultry flocks, its labeling bears adequate directions and warnings for such use, and it contains one, but only one, of the following ingredients in a quantity, by weight of feed, as hereinafter indicated:

(i) Sulfaquinoxaline: Not less than 0.033 percent and not more than 0.10 percent.

(ii) Nitrophenide: 0.05 percent.

(iii) Nitrofurazone: 0.0112 percent.

(3) It is intended for use solely in the prevention of outbreaks of histomoniasis ("blackhead") in turkey flocks, its labeling bears adequate directions and warnings for such use, and it contains one, but only one, of the following ingredients in a quantity, by weight of feed, as hereinafter indicated:

(i) 2-Amino-5-nitrothiazole: 0.05 percent.

(ii) 4-Nitrophenylarsonic acid: 0.025 percent.

(iii) Furazolidone: 0.011 percent.

(4) It is intended for use solely in the control of outbreaks of histomoniasis ("blackhead") in turkey flocks, its labeling bears adequate directions and warnings for such use, and it contains 2-amino-5-nitrothiazole in a quantity, by weight of feed, of 0.10 percent.

(5) It is intended for use solely as an anthelmintic for poultry or swine, its labeling bears adequate directions and warnings for such use, and it contains one, but only one, of the following ingredients in a quantity, by weight of feed, as hereinafter indicated:

(i) di-*N*-Butyl tin dilaurate 0.07 percent, nicotine 0.03 percent, and phenothiazine 0.29 percent.

(ii) Nicotine 0.067 percent, phenothiazine 0.60 percent, and 2,2'dihydroxy-5,5'dichlorodiphenylmethane 0.28 percent.

(iii) Phenothiazine, not less than 0.3 percent and not more than 1.0 percent, and nicotine, not less than 0.03 percent and not more than 0.07 percent.

(iv) Phenothiazine, not less than 0.3 percent and not more than 1.0 percent.

(v) Nicotine, not less than 0.03 percent and not more than 0.07 percent.

(vi) Sodium fluoride 0.3 percent and sodium sulfate 2.0 percent.

(vii) Cadmium anthranilate, 0.044 percent.

(viii) Cadmium oxide, 0.015 percent.

(ix) Sodium fluoride, not less than 0.5 percent and not more than 1.0 percent.

(6) It is intended for use solely in the prevention of chronic respiratory disease (air-sac infection) and hexamitiasis in poultry, infectious swine enteritis, and/or calf scours; its labeling bears adequate directions and warnings for such use; and it contains not less than 50 grams of chlortetracycline per ton of feed. When intended for such uses it may also contain oxytetracycline in a quantity not less than 50 grams per ton of feed and, in the amount specified, one, but only one, of the ingredients prescribed by paragraph (a) of this section.

(7) It is intended for use solely as a treatment for chronic respiratory disease (air-sac infection), sinusitis, nonspecific infectious enteritis, blue comb, mud fever, and hexamitiasis in poultry, and/or infectious swine enteritis; its labeling bears adequate directions and warnings for such use, and it contains, per ton of feed, not less than 100 grams of chlortetracycline or not less than 75 grams of streptomycin and 15 grams of penicillin. When intended for such uses it may also contain oxytetracycline in a quantity not less than 100 grams per ton of feed and, in the amount specified, one, but only one, of the ingredients prescribed by paragraph (a) of this section. If it is intended for use solely in poultry, it may contain 0.1 percent of para-aminobenzoic acid or the sodium or potassium salt of para-aminobenzoic acid, or if it is intended for continuation of coccidiosis prevention it shall contain, in the amount specified, one of the ingredients prescribed by subparagraph (1) of this paragraph.

(8) It is intended for use solely in the prevention of coccidiosis and hexamitiasis outbreaks in turkey flocks, its labeling bears adequate directions and warnings for such use, and it contains di-*N*-butyl tin dilaurate in a quantity, by weight of feed, of 0.0375 percent.

(9) It is intended for use solely in the prevention of infectious swine enteritis, its labeling bears adequate directions and warnings for such use, and it contains not less than 50 grams of bacitracin activity per ton of feed.

(10) It is intended for use solely as a treatment for infectious swine enteritis, its labeling bears adequate directions and warnings for such use, and it contains not less than 100 grams of bacitracin activity per ton of feed.

(11) It is intended for use solely as a treatment for infectious swine enteritis caused by Salmonella choleraesuis, its labeling bears adequate directions and warnings for such use, and it contains nitrofurazone in a quantity, by weight of feed, of 0.056 percent.

(12) It is intended for use solely in the prevention of coccidiosis, chronic respiratory disease (air-sac infection) and hexamitiasis in poultry; its labeling bears adequate directions and warnings for such use; and it contains, in the amount specified, one of the ingredients prescribed by subparagraph (1) of this paragraph and not less than 50 grams of chlortetracycline per ton of feed. When intended for such uses it may also contain oxytetracycline in a quantity not less than 50 grams per ton of feed.

(13) It is intended for use solely in the prevention or treatment of chronic respiratory disease (air-sac infection) and sinusitis in poultry; its labeling bears adequate directions and warnings for such use; and it contains not less than 0.1 percent para-aminobenzoic acid or the sodium or potassium salt of para-aminobenzoic acid.

(14) It is intended solely as an aid in the prevention and control of losses due to low-grade bacterial enteritis in mink; its labeling bears adequate directions and warnings for such use; and it contains not less than 5.7 grams of chlortetracycline, 1.0 gram of bacitracin, and 0.75 gram of penicillin (with or without oxytetracycline) per ton of feed.

(15) It is intended for use solely in the prevention or treatment of fowl typhoid, pullorum, and the paratyphoids in poultry; its labeling bears adequate

directions and warnings for such use; and it contains furazolidone in a quantity, by weight of feed, of 0.0055 percent, if intended for the prevention of the diseases in birds older than 2 weeks, or 0.011 percent, if intended for prevention of the diseases in birds younger than 2 weeks, or for the treatment of the diseases.

(16) It is intended for use solely in the prevention of chronic respiratory disease (air-sac infection), hexamitiasis, fowl typhoid, pullorum, and the paratyphoids in poultry; its labeling bears adequate directions and warnings for such uses; it contains not less than 50 grams of chlortetracycline per ton of feed (except that it may contain not less than 25 grams of chlortetracycline per ton of feed if it also contains not less than 25 grams of oxytetracycline per ton of feed); and it contains furazolidone in a quantity, by weight of feed, of 0.0055 percent, if intended for prevention of the diseases in birds older than 2 weeks, or 0.011 percent, if intended for prevention of the diseases in birds younger than 2 weeks. When intended for such uses it may also contain the equivalent of not less than 50 grams of bacitracin per ton of feed.

(17) It is intended for use solely as a treatment for chronic respiratory disease (air-sac infection), sinusitis, nonspecific infectious enteritis, blue comb, mud fever, hexamitiasis, fowl typhoid, pullorum, and the paratyphoids in poultry; its labeling bears adequate directions and warnings for such uses; it contains not less than 100 grams of chlortetracycline per ton of feed (except that the quantity of chlortetracycline may be 50 grams per ton if it also contains 50 grams per ton of oxytetracycline); and it contains furazolidone in a quantity, by weight of feed, of 0.011 percent. When intended for such uses it may also contain the equivalent of not less than 100 grams of bacitracin per ton of feed.

(18) It is intended for use solely in the prevention of chronic respiratory disease (air-sac infection), nonspecific enteritis, infectious sinusitis, and blue comb in poultry; its labeling bears adequate directions and warnings for such use; and it contains the equivalent of not less than 50 grams of penicillin G master standard per ton of feed.

(19) It is intended for use solely in the treatment of chronic respiratory disease (air-sac infection), nonspecific enteritis, infectious sinusitis, and blue comb in poultry; its labeling bears adequate directions and warnings for such use; and it contains the equivalent of not less than 100 grams of penicillin G master standard per ton of feed.

(20) (i) It is intended for use solely in the prevention of outbreaks of coccidiosis in poultry flocks, and it contains nicarbazin (4,4′-dinitrocarbanilide complex with 2-hydroxy-4-6-dimethylpyrimidine) in a quantity, by weight of feed, of not less than 0.01 percent and not more than 0.02 percent, or arsenosobenzene in a quantity, by weight of feed, of 0.002 percent, or 2,4-diamino-5-(*p*-chlorophenyl)-6-ethylpyrimidine in a quantity, by weight of feed, of 0.00075 percent and sulfaquinoxaline in a quantity, by weight of feed, of 0.0075 percent; and there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in § 146.7 to establish the safety and efficacy of the article and to guarantee its identity, strength, quality, and purity. The exemption shall expire at the beginning of any act changing the composition or labeling of such drug or the methods used in its manufacturing, processing, or packaging or the facilities and controls used for such manufacturing, processing, or packaging, unless the person who obtained the exemption has submitted to the Commissioner, in triplicate, amended information describing such proposed changes, and such amendment has been accepted by the Commissioner.

(ii) It is also intended for the prevention or treatment of the diseases of poultry specified in subparagraphs (6) and (7) or (16) and (17) of this paragraph, it contains one of the ingredients in the amount and under the conditions set forth in subdivision (i) of this subparagraph, and it contains the ingredients in the amounts specified in subparagraphs (6) and (7) or (16) and (17) of this paragraph, except that the coccidiostat shall be only one of those specified in subdivision (i) of this subparagraph.

(iii) It is intended for use in the diseases specified in subdivisions (i) and (ii) of this subparagraph, it contains ingredients in the amounts and under the conditions specified in those subdivisions, and it contains one, but only one, of the ingredients prescribed by paragraph (a) of this section and in the amounts specified in that paragraph.

(21) It is intended for use solely in the prevention or treatment of chronic respiratory disease (air-sac infection), blue comb, and infectious sinusitis in poultry; its labeling bears adequate directions and warnings for such uses; and it contains, per ton of feed, not less than 50 grams of bacitracin activity, if intended for prevention, and not less than 100 grams of bacitracin activity, if intended for the treatment of these diseases.

(22) It is intended for use solely in the prevention or control of outbreaks of histomoniasis ("blackhead") in turkey flocks, and it contains 2-acetylamino-5-nitrothiazole in a quantity, by weight of feed, of 0.015 percent if intended for the prevention of the disease, or 0.05 percent if intended for the control of the disease, and there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in § 146.7 to establish the safety and efficacy of the article and to guarantee its identity, strength, quality, and purity. The exemption shall expire at the beginning of any act changing the composition of such drug, or the methods used in, and the facilities and controls used for its manufacturing, processing, and packaging, or in its labeling, unless the person who obtained the exemption has submitted to the Commissioner, in triplicate, amended information that describes such proposed changes, and such amendment has been accepted by the Commissioner.

(23) It is intended as an aid in stimulating growth, the prevention of coccidiosis, large roundworms and tapeworms in chickens and turkeys and the prevention of hexamitiasis in turkeys, and it contains in a quantity, by weight of feed, acetyl (*p*-nitrophenyl) sulfanilamide 0.03 percent, dibutyl tin dilaurate 0.02 percent, dinitrodiphenylsulfonylethylenediamine 0.02 percent, and 3-nitro-4-hydroxyphenylarsonic acid 0.0075 percent.

(24) (i) It is intended for promoting distribution of fat in chickens and turkeys, it contains dienestrol diacetate in a quantity, by weight of feed, of 0.007 percent, and there has been submitted to the Commissioner, in triplicate, adequate information of the kind described in § 146.7, to establish the safety and efficacy of the article and to guarantee its identity, strength, quality, and purity. The exemption shall expire at the beginning of any act changing the composition or labeling of such drug, or the methods used in its manufacturing, processing, or packaging, or the facilities and controls used for such manufacturing, processing, or packaging, unless the person who obtained the exemption has submitted to the Commissioner, in triplicate, amended information describing such proposed changes, and such amendment has been accepted by the Commissioner.

(ii) It is also intended for the prevention or treatment of the diseases of poultry specified in subparagraphs (6) and (7) of this paragraph, it contains dienestrol diacetate in the amounts and under the conditions set forth in subdivision (i) of this subparagraph, and it contains the antibiotics in the amounts specified in subparagraphs (6) and (7) of this paragraph.

(iii) It is also intended for continuation of coccidiosis prevention in poultry, it contains dienestrol diacetate in the amounts and under the conditions set forth in subdivision (i) of this subparagraph, and it contains one, but only one, of the ingredients prescribed by subparagraph (1) of this paragraph and in the amounts specified in that subparagraph, or it contains one, but only one, of the coccidiostats prescribed by subparagraph (20) of this paragraph, and in the amounts specified in that subparagraph.

(iv) It is intended for use in the diseases specified in subdivisions (i), (ii), and (iii) of this subparagraph, it contains ingredients in the amounts and under the conditions specified in those subdivisions, and it contains one, but only one, of the ingredients prescribed by paragraph (a) of this section, and in the amounts specified in that paragraph.

(25) (i) It is intended for use solely in the control of outbreaks of coccidiosis in poultry flocks and it contains in a quantity, by weight of feed, not less than 0.003 percent and not more than 0.006 percent of 2,4-diamino-5-(*p*-chlorophenyl)-6-ethylpyrimidine and not less than 0.01 percent and not more than 0.02 percent of sulfaquinoxaline, and there has been submitted to the Commissioner, in triplicate, the information

referred to in § 146.7, as well as any additional information necessary to establish the safety and efficacy of the article and to guarantee its identity, strength, quality, and purity. The exemption shall expire at the beginning of any act changing the composition or labeling of such drug or the methods used in its manufacturing, processing, or repackaging, or the facilities and controls used for such manufacturing, processing, or repackaging, unless the person who obtains the exemption has submitted to the Commissioner, in triplicate, amended information describing such proposed changes and such amendment has been accepted by the Commissioner.

(ii) It is intended for use in the disease specified in subdivision (i) of this subparagraph, it contains the ingredients in the amounts and under the conditions specified in that subdivision, and it contains one, but only one, of the ingredients prescribed by paragraph (a) of this section and in the amounts specified in that paragraph.

§ 146.27 *Antibiotics for fish diseases.* Penicillin, streptomycin, dihydrostreptomycin, chlortetracycline, tetracycline, chloramphenicol, or bacitracin intended for use solely in the treatment or prevention of disease in fish and conspicuously so labeled shall be exempt from the requirements of sections 502 (l) and 507 of the act.

§ 146.28 *Antibiotics for bull semen.* Penicillin, streptomycin, dihydrostreptomycin, chlortetracycline, chloramphenicol, or bacitracin intended for use solely as a preservative for bull semen, and conspicuously so labeled, shall be exempt from the requirements of sections 502 (l) and 507 of the act.

§ 146.29 *Biological drugs that contain antibiotics.* Biological drugs that contain penicillin, streptomycin, dihydrostreptomycin, chlortetracycline, bacitracin, or chloramphenicol, and the purpose of the antibiotic is for use only as a preservative and the biological drug is conspicuously so labeled, shall be exempt from the requirements of sections 502 (l) and 507 of the act, if such drugs are licensed under the Public Health Service Act of July 1, 1944 (58 Stat. 682; 42 U. S. C. 201 et seq.) or under the Virus-Serum-Toxin Act of March 4, 1913 (37 Stat. 832; 21 U. S. C. 151 et seq.).

PART 146a—CERTIFICATION OF PENICILLIN-CONTAINING DRUGS

Sec.
146a.24 Sodium penicillin, calcium penicillin, crystalline penicillin.
146a.25 Penicillin in oil and wax.
146a.26 Penicillin ointment.
146a.27 Penicillin tablets.
146a.28 Crystalline penicillin G oral suspension, crystalline penicillin G sodium oral suspension, potassium penicillin G oral suspension.
146a.29 Penicillin with aluminum hydroxide gel.
146a.30 Penicillin troches.
146a.31 Penicillin dental cones.
146a.32 Pencillin with vasoconstrictor; penicillin with ____.
146a.33 Penicillin for surface application.
146a.34 Tablets aluminum penicillin.
146a.35 Penicillin sulfonamide powder.
146a.36 Penicillin vaginal suppositories.
Sec.
146a.37 Buffered crystalline penicillin.
146a.38 Capsules buffered penicillin with pectin hydrolysate.
146a.39 Capsules procaine penicillin in oil.
146a.40 Penicillin bougies.
146a.41 Crystalline penicillin and epinephrine in oil.
146a.42 Aluminum penicillin.
146a.43 Aluminum penicillin in oil.
146a.44 Procaine penicillin, procaine penicillin G.
146a.45 Procaine penicillin in oil.
146a.46 Crystalline penicillin for inhalation therapy.
146a.47 Procaine penicillin for aqueous injection.
146a.48 Ephedrine penicillin, ephedrine penicillin G.
146a.49 Ephedrine penicillin tablets.
146a.50 Procaine penicillin and buffered crystalline penicillin for aqueous injection.
146a.51 Buffered penicillin powder, penicillin powder with buffered aqueous diluent.
146a.52 Procaine penicillin and crystalline penicillin in oil.
146a.54 Penicillin - streptomycin ointment; penicillin - dihydrostreptomycin ointment.
146a.55 Penicillin - streptomycin bougies; penicillin - dihydrostreptomycin bougies.
146a.56 Penicillin-bacitracin ointment.
146a.57 Procaine penicillin and streptomycin in oil; procaine penicillin and dihydrostreptomycin in oil.
146a.58 Penicillin and streptomycin; penicillin and dihydrostreptomycin.
146a.59 Penicillin tooth powder.
146a.60 Penicillin-bacitracin troches.
146a.63 Crystalline penicillin and bacitracin.
146a.64 *l*-Ephenamine penicillin G.
146a.65 *l*-Ephenamine penicillin G in oil.
146a.66 *l*-Ephenamine penicillin G for aqueous injection.
146a.67 Procaine penicillin in streptomycin sulfate solution; procaine penicillin in dihydrostreptomycin sulfate solution.
146a.68 Benzathine penicillin G.
146a.69 Benzathine penicillin G oral suspension; benzathine penicillin G for oral suspension.
146a.70 Penicillin - streptomycin - bacitracin ointment; penicillin-dihydrostreptomycin - bacitracin ointment.
146a.71 Penicillin-streptomycin dental cones; penicillin-dihydrostreptomycin dental cones.
146a.74 Diethylaminoethyl ester penicillin G hydriodide.
146a.75 Diethylaminoethyl ester penicillin G hydriodide for aqueous injection.
146a.76 Penicillin-streptomycin implantation pellets; penicillin-dihydrostreptomycin implantation pellets.
146a.77 Benzathine penicillin G for aqueous injection.
146a.78 Benzathine penicillin G and buffered crystalline penicillin for aqueous injection.
146a.79 Chloroprocaine penicillin O.
146a.80 Chloroprocaine penicillin O for aqueous injection.
146a.81 Penicillin-streptomycin vaginal suppositories; penicillin-dihydrostreptomycin vaginal suppositories.
146a.82 Penicillin-streptomycin - bacitracin dental paste; penicillin-dihydrostreptomycin-bacitracin dental paste.
146a.84 Penicillin and dihydrostreptomycin-streptomycin sulfates, procaine penicillin in dihydrostreptomycin-streptomycin sulfates solution.
Sec.
146a.85 Benzathine procaine-buffered crystalline penicillins for aqueous injection.
146a.86 Benzathine penicillin G and procaine penicillin for aqueous injection.
146a.87 Penicillin - bacitracin - neomycin ointment; penicillin-bacitracin-neomycin in oil.
146a.88 Penicillin - streptomycin tablets; penicillin - dihydrostreptomycin tablets.
146a.89 Procaine penicillin - streptomycin-neomycin in oil; procaine penicillin - dihydrostreptomycin - neomycin in oil; procaine penicillin-streptomycin-neomycin ointment; procaine penicillin-dihydrostreptomycin-neomycin ointment.
146a.90 Procaine penicillin and benzathine penicillin G in streptomycin sulfate solution; procaine penicillin and benzathine penicillin G in dihydrostreptomycin sulfate solution.
146a.91 Benzathine penicillin G and streptomycin; benzathine penicillin G and dihydrostreptomycin.
146a.92 Tablets benzathine penicillin G and crystalline penicillin.
146a.93 Penicillin - streptomycin powder; penicillin - dihydrostreptomycin powder.
146a.94 Dibenzylamine penicillin G.
146a.95 Dibenzylamine penicillin and potassium penicillin powder, buffered.
146a.96 Dibenzylamine penicillin and streptomycin in oil; dibenzylamine penicillin and dihydrostreptomycin in oil.
146a.97 Hydrabamine penicillin G.
146a.98 Hydrabamine penicillin G oral suspension.
146a.99 Capsules crystalline penicillin G.
146a.100 Benzathine penicillin G in oil.
146a.101 Benzathine penicillin G and procaine penicillin G in oil.
146a.102 Benzathine penicillin G-procaine penicillin G-streptomycin in oil; benzathine penicillin G-procaine penicillin G-dihydrostreptomycin in oil.
146a.103 Penicillin V (phenoxymethyl penicillin).
146a.106 Tablets benzathine penicillin G and penicillin V.
146a.107 Capsules penicillin V.
146a.108 Procaine penicillin-streptomycin-polymyxin in oil; procaine penicillin - dihydrostreptomycin-polymyxin in oil.

AUTHORITY: §§ 146a.24 to 146a.108 issued under sec. 701, 52 Stat. 1055; 21 U. S. C. 371. Interpret or apply sec. 507, 59 Stat. 463, as amended; 21 U. S. C. 357.

§ 146a.24 *Sodium penicillin (penicillin sodium, penicillin sodium salt), calcium penicillin (penicillin calcium, penicillin calcium salt), crystalline penicillin (crystalline penicillin sodium, crystalline penicillin sodium salt, crystalline penicillin potassium, crystalline penicillin potassium salt, crystalline penicillin G sodium, crystalline penicillin G sodium salt, crystalline penicillin G potassium, crystalline penicillin G potassium salt, crystalline penicillin O sodium, crystalline penicillin O sodium salt, crystalline penicillin O potassium, crystalline penicillin O potassium salt)*—(a) *Standards of identity, strength, quality, and purity.* Sodium penicillin is the sodium salt of a kind of penicillin, or a mixture of two or more such salts; calcium penicillin is the calcium salt of a kind of penicillin, or a mixture of two or more such salts; crystalline penicillin is the heat-stable crystalline sodium or potassium salt of one or more kinds of penicillin, but the quantity of any salt of penicillin K therein is not more than 30 percent; crystalline penicillin G is crystalline penicillin which contains not less than 85 percent by weight of the sodium salt or potassium salt of penicillin G; crystalline penicillin O is crystalline penicillin which contains not less than 85 percent by weight of the sodium salt or potassium salt of penicillin O and it contains not more than 0.5 percent by weight of the sodium salt or potassium salt of penicillin G. Each such drug is so purified and dried that:

(1) Its potency is not less than 500 units per milligram, except that if it contains not less than 90 percent of a salt of penicillin X its potency is not less than 350 units per milligram;

(2) It is sterile;

(3) It is nontoxic;

(4) It is nonpyrogenic;

(5) Its moisture content is not more than 2.5 percent unless it is crystalline penicillin in which case its moisture content is not more than 1.5 percent;

(6) Its pH in aqueous solution of 5,000 to 10,000 units per milliliter is not less than 5.0 and not more than 7.5.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing it shall be in immediate containers of colorless transparent glass, closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness; each such container shall contain 100,000 units, 200,000 units, 300,000 units, 500,000 units, 1,000,000 units, 2,000,000 units, 3,000,000 units, 4,000,000 units, or 5,000,000 units, except that when packaged and labeled solely for dental use each such container may contain not less than 10,000 units, and each may be packaged in combination with a container of the solvent, water for injection U. S. P., dextrose injection 5 percent U. S. P. (if not packaged for dental use), physiological salt solution U. S. P., or an aqueous solution of a suitable local anesthetic.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in the immediate container;

(iii) The statement "Expiration date --------," the blank being filled in with the date which is 18 months or if it is crystalline penicillin 36 months, after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) The statement "For Manufacturing Use," "For Repacking," or "For Manufacturing Use or Repacking" when packaged for repacking or for use as an ingredient in the manufacture of another drug, as the case may be.

(2) On the immediate container, the statement "Sterile solution may be kept in refrigerator for ------ days without significant loss of potency," the blank being filled in with the figure "3" if it is crystalline penicillin or with the figure "7" if it is not crystalline penicillin, unless such information is contained in the labeling within the package from which it is dispensed.

(3) On the outside wrapper or container:

(i) If it is not crystalline penicillin, the statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)."

(ii) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(iii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification, check tests and assays; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of units in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, sterility, toxicity, pyrogens, moisture, pH, penicillin K content (unless it is crystalline penicillin G or crystalline penicillin O), crystallinity and heat stability if it is crystalline penicillin, the penicillin G content if it is crystalline penicillin G or crystalline penicillin O, and the penicillin O content if it is crystalline penicillin O. If such batch or any part thereof is to be packaged with a solvent such request shall also be acompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) If such batch is packaged for dispensing, such person shall submit with his request a sample consisting of 10 immediate containers for sterility testing and, for all tests except sterility, one immediate container for each 5,000 immediate containers in the batch but in no case less than or more than the following quantities (excluding the 10 containers submitted for sterlity):

(i) If it is not crystalline penicillin, not less than 6 or more than 13 immediate containers;

(ii) If it is crystalline penicillin, other than crystalline penicillin G or crystalline penicillin O, not less than 8 or more than 15 immediate containers;

(iii) If it is crystalline penicillin G or crystalline penicillin O, not less than 10 or more than 17 immediate containers; or

(iv) If it is packaged in containers of less than 100,000 units each for dental use, not less than 20 or more than 100 immediate containers if it is not crystalline penicillin, and not less than 40 or more than 100 immediate containers if it is crystalline penicillin.

Such sample shall be collected by taking single immediate containers before or after labeling, at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(3) If such batch is packaged for repacking or for use in the manufacture of another drug, such person shall submit with his request an accurately representative sample of the batch, consisting of the following:

(i) For all tests except sterility; 6 packages, or in the case of crystalline penicillin 10 packages, containing approximately equal portions of not less than 60 milligrams each.

(ii) For sterility testing; 10 packages, each containing approximately 300 milligrams.

Each such portion shall be taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(4) In connection with contemplated requests for certification of repacked batches or batches of another drug in the manufacture of which it is to be used, the manufacturer of a batch which is to be so repacked or used may request the Commissioner to make check tests and assays on a sample of such batch taken as prescribed by subparagraph (3) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such

manufacturer results of such check tests and assays as are so requested.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (2) (i), (ii), and (iii), (3) (i), and (4) of this section; $1.00 for each immediate container in the sample submitted in accordance with paragraph (d) (2) (iv) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

(f) *Exemption of crystalline penicillin G from certification.* Crystalline penicillin G sodium, crystalline penicillin G sodium salt, crystalline penicillin G potassium, crystalline penicillin G potassium salt, shall be exempt from the requirements of sections 502 (l) and 507 of the act. No provision of any regulation in this part shall apply to such drug except the standards of identity, strength, quality, and purity specified for its use in the manufacture of another drug.

§ 146a.25 *Penicillin in oil and wax (calcium penicillin in oil and wax, crystalline penicillin in oil and wax)*—(a) *Standards of identity, strength, quality, and purity.* Penicillin in oil and wax is a suspension of calcium penicillin or crystalline penicillin in a menstruum of refined peanut oil or sesame oil in which white wax is dispersed. If it is represented to be free-flowing, not less than 50 percent of the total relative weight of the penicillin in the drug consists of penicillin having a particle size of not less than 50 microns in length. Its potency is 100,000 units, 200,000 units, or 300,000 units per milliliter except if it is packaged and labeled solely for udder instillations of cattle its potency is 2,000 units per milliliter. The content of white wax in the menstruum before the addition of the penicillin is not less than 3.0 percent (w/v) if the potency is to be not more than 200,000 units per milliliter, and not less than 4.7 or more than 4.9 percent (w/v) if the potency is to be 300,000 units per milliliter. The moisture content is not more than 1.0 percent. It is sterile. The calcium penicillin or crystalline penicillin used conforms to the requirements of § 146a.24 (a), but its potency is not less than 750 units per milligram if it is used in making a product of not more than 200,000 units per milliliter, and not less than 900 units per milligram if it is used in making a product containing 300,000 units per milliliter. The peanut oil, sesame oil, and the white wax used conform to the standards prescribed therefor by the U. S. P.

(b) *Packaging.* The immediate container of penicillin in oil and wax shall be of colorless transparent glass (if packaged and labeled solely for udder instillations of cattle, it shall be of transparent glass) so closed as to be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that its contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The quantity of penicillin in oil and wax in each such container shall be not less than one milliliter and not more than 20 milliliters, unless it is packaged for repacking or is packaged and labeled solely for udder instillations of cattle. Unless it is packaged for repacking each container shall be filled with a volume of penicillin in oil and wax in excess of that designated, which excess shall be sufficient to permit the withdrawal and the administration of the volume indicated whether administered in either single or multiple doses.

(c) *Labeling.* Each package of penicillin in oil and wax shall bear, on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container of the package:

(i) The batch mark;

(ii) The number of units per milliliter of the batch;

(iii) The statement "Expiration date ---------," the blank being filled in, if crystalline penicillin is used, with the date which is 18 months, or if crystalline penicillin is not used, with the date which is 12 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) The statement "For intramuscular use only";

(v) If it is represented to be free-flowing, the statements "Do not heat" and "Shake well";

(vi) If it is represented to contain 2,000 units per milliliter, the statement "For udder instillations of cattle only"; and

(vii) The name of each oil used in making the batch.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of penicillin in oil and wax shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each of such packages, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that the peanut oil or sesame oil and white wax used in making such batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, moisture, and if it is represented to be free-flowing, the particle size of the penicillin.

(ii) The penicillin used in making the batch; potency, sterility, toxicity, pyrogens, moisture, pH, penicillin K content (unless it is crystalline penicillin G), crystallinity and heat stability if it is crystalline penicillin, and the penicillin G content if it is crystalline penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility; one package for each 500 packages in the batch, but in no case less than 3 packages, except if it is represented to be free flowing, in which case not less than 4 packages or more than 12 packages.

(*b*) For sterility testing; 10 packages. Such samples shall be collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The penicillin used in making the batch:

(*a*) For all tests except sterility; 6 packages if it is calcium penicillin or 10 packages if it is crystalline penicillin, each containing approximately equal portions of not less than 60 milligrams.

(*b*) For sterility testing; 10 packages, each containing approximately equal portions of not less than 300 milligrams. Such samples shall be packaged in accordance with the requirements of § 146a.24 (b).

(iii) In case of an initial request for certification, the peanut oil or sesame oil and white wax used in making the batch; one package of each containing, respectively, approximately 250 grams and 25 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin in oil and wax under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i) (*a*), and (ii) (*a*), and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fees prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.26 *Penicillin ointment*—(a) *Standards of identity, strength, quality, and purity.* Penicillin ointment is calcium penicillin, crystalline penicillin, procaine penicillin, or *l*-ephenamine penicillin G in a suitable and harmless ointment base, with or without a suitable anesthetic. If it is intended solely for veterinary use and is conspicuously so labeled, it may contain nitrofurazone and a suitable and harmless salt of cobalt. Its moisture content is not more than 1.0 percent. Its potency is not less than 250 units per gram, except if it is packaged and labeled solely for udder instillations of cattle, its potency is not less than 2,000 units per gram. The calcium penicillin or crystalline penicillin used conforms to the requirements of § 146a.24 (a), except the limitation on penicillin K content, and except subparagraphs (1), (2), and (4) of that paragraph, but its potency is not less than 300 units per milligram. The procaine penicillin used conforms to the requirements of § 146a.44 (a), except subparagraphs (2) and (3) of that paragraph. The *l*-ephenamine penicillin G used conforms to the requirements of § 146a.64 (a), except § 146a.64 (a) (2) and (3). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless it is intended solely for veterinary use, penicillin ointment shall be packaged in collapsible tubes, which shall be well-closed containers as defined by the U. S. P., and shall not be larger than the ⅛-ounce size if such ointment is represented for ophthalmic use, and in no case larger than the 2-ounce size. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of penicillin ointment shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units per gram of the batch;

(iii) The statement "Expiration date ____________," the blank being filled in with the date which is not more than 12 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 18 or 24 or 36 months after the month during which the batch was certified, if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) If it is labeled solely for udder instillations of cattle and is packaged in glass containers, the statements "Not for injection," "For udder instillations of cattle only," and "Shake well";

(v) If the batch contains in addition to penicillin one or more other active ingredients specified in paragraph (a) of this section, the name and quantity of each such other ingredient per gram of the batch.

(2) On the outside wrapper or container:

(i) The statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)," unless the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section after having been stored at room temperature, but in no case shall such statement be required if it is labeled with an expiration date which is 9 months after the month during which the batch was certified;

(ii) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(iii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of penicillin ointment shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that each component of the ointment base used conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency and moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, crystallinity if it is a crystalline salt of penicillin, heat stability if it is crystalline penicillin or *l*-ephenamine penicillin G, the penicillin G content if it is penicillin G, and the specific rotation if it is *l*-ephenamine penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one package for each 5,000 packages in the batch, but in no case less than 5 packages or more than 12 packages, collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The penicillin used in making the batch; 5 packages, or in the case of crystalline penicillin, 10 packages, each containing approximately equal portions of not less than 60 milligrams if it is not procaine penicillin, and not less than 300 milligrams if it is procaine penicillin, packaged in accordance with the requirements of § 146a.24 (b) or § 146a.44 (b).

(iii) In case of an initial request for certification, the ingredients used in making the batch; one package of each containing approximately 200 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin ointment under the regulations in this part shall be:

(1) $4.00 for each package in the sample submitted in accordance with paragraph (d) (3) (i) of this section, $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii), of this section; and

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.27 *Penicillin tablets*—(a) *Standards of identity, strength, quality, and purity.* Penicillin tablets are tablets composed of sodium penicillin, calcium penicillin, potassium penicillin, crystalline penicillin O, crystalline penicillin V, benzathine penicillin G, or procaine penicillin, with or without one or more suitable analgesic substances, antihistaminics, and caffeine and with or without one or more suitable and harmless vitamin substances, buffer substances, diluents, binders, lubricants, colorings, and flavorings. They may also contain probenecid or one or more suitable sulfonamides. The potency of each tablet is not less than 50,000 units, and if it is less than 100,000 units it is unscored. Its moisture content is not more than 1.0 percent if it contains sodium penicillin, calcium penicillin, potassium penicillin, or crystalline penicillin O; not more than 2.0 percent if it contains procaine penicillin; not more than 3.0 percent if it contains crystalline penicillin V; and not more than 8.0 percent if it contains benzathine penicillin G. The penicillin used conforms to the standards prescribed for such drug by the regulations in this chapter, except the standards for sterility and pyrogens. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each penicillin tablet is enclosed in a foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the tablets by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. If the penicillin tablets are freely soluble, each immediate container may be packaged in combination with one immediate container of a suitable and harmless aqueous vehicle with or without one or more suitable sulfonamides.

(c) *Labeling.* Each package of penicillin tablets shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in each tablet of the batch;

(iii) If the batch contains, in addition to penicillin, one or more of the other active ingredients specified in paragraph (a) of this section, the name and quantity of each such other ingredient in each tablet.

(iv) If the batch contains buffer substances, the name of each such substance used in making the batch;

(v) If it is a packaged combination of penicillin tablets and a vehicle with or without sulfonamides, a statement giving the method of dissolving the penicillin; and

(vi) The statement "Expiration date ----------------," the blank being filled in with one of the following dates after the month during which the batch was certified:

(*a*) If a crystalline penicillin is not used, 12 months.

(*b*) If a crystalline penicillin is used and it contains a vitamin substance, 18 months.

(*c*) If a penicillin V is used, and it does not contain a vitamin substance, 24 months.

(*d*) If a crystalline penicillin other than a penicillin V is used and it does not contain a vitamin substance, 36 months.

(*e*) In lieu of the expiration date prescribed above for a drug, if the person who requests certification has submitted to the Commissioner results of tests and assays that show such drug as prepared by him is stable for 24 months, 36 months, 48 months, or 60 months, such date may be used for such drug:

Provided, however, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the label and labeling, if it contains, in addition to penicillin, one or more of the other active ingredients specified in paragraph (a) of this section, after the name "penicillin tablets," wherever it appears, the words "with ------ (the blank being filled in with the common or usual name of each such other ingredient)" in juxtaposition with such name.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of penicillin tablets shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each tablet, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per tablet and average moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, penicillin K content (unless it is crystalline penicillin G, crystalline penicillin O, or crystalline penicillin V), crystallinity if it is crystalline penicillin; heat stability if it is crystalline sodium penicillin, potassium penicillin, or crystalline penicillin O; the penicillin G content if it is a penicillin G or crystalline penicillin O; the penicillin V content if it is a penicillin V; and the penicillin O content if it is crystalline penicillin O.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one tablet for each 5,000 tablets in the batch, but in no case less than 20 tablets or more than 100 tablets, collected by taking single tablets at such intervals throughout the entire time of tableting that the quantities tableted during the intervals are approximately equal.

(ii) The penicillin used in making the batch; 6 packages, or in the case of crystalline penicillin 10 packages, each containing approximately equal portions of not less than 60 milligrams, except that if it is procaine penicillin, benzathine penicillin G, or penicillin V each package shall contain not less than 300 milligrams, packaged in accordance with the requirements of § 146a.24 (b), 146a.44 (b), 146a.68 (b), or 146a.103 (b).

(iii) In case of an initial request, each other substance used in making the batch; one package of each, containing approximately 5 gm., and if the batch or any part thereof is to be packaged in combination with an aqueous vehicle, or when any change is made in the composition of such vehicle, five packages of the vehicle included in the combination.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin tablets under the regulations in this part shall be:

(1) $1.00 for each tablet in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such tablets and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification, unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

(f) *Exemption of penicillin tablets from certification.* Penicillin tablets, with or without added vitamin substances and residues from streptomyces fermentation, shall be exempt from the requirements of sections 502 (l) and 507 of the act, if they comply with the following conditions:

(1) They contain not more than 1,000 units per tablet.

(2) The outside wrapper or container and the immediate container bear an expiration date that is not more than 36 months after the month during which the batch was last assayed and released by the manufacturer.

(3) They are intended to be administered only in the drinking water of poultry for use solely as a feed supplement and are conspicuously so labeled; they are not represented for the prevention or treatment of disease; and their labeling bears adequate directions for use by laymen.

§ 146a.28 *Crystalline penicillin G oral suspension, crystalline penicillin G sodium oral suspension, potassium penicillin G oral suspension*—(a) *Standards of identity, strength, quality, and purity.* Crystalline penicillin G oral suspension is crystalline penicillin G sodium or potassium penicillin G and one or more suitable and harmless suspending or dispersing agents and preservatives, with or without probenecid or one or more suitable sulfonamides and suitable and harmless buffer substances, colorings, and flavorings, suspended in a suitable and harmless vehicle. Its potency is not less than 20,000 units per milliliter. Its moisture content is not more than 1.0 percent. The crystalline penicillin used conforms to § 146a.24 (a), except § 146a.24 (a) (2) and (4). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* The immediate container shall be a tight container as defined by the U. S. P., and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of units in each milliliter of the batch.

(iii) The name of each buffer substance, the quantity of probenecid, and the name and quantity of each sulfonamide and preservative used in making the batch.

(iv) The statement "Shake well."

(v) The statement "Expiration date ________," the blank being filled in with the date which is 24 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the label and labeling, if it contains, in addition to penicillin, one or more of the other active ingredients specified in paragraph (a) of this section, after the name "crystalline penicillin G oral suspension," wherever it appears, the words "with ——— (the blank being filled in with the common or usual name of each such other ingredient)," in juxtaposition with such name.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin G used in making such batch was completed, the potency per milliliter of the batch, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch, and a statement that each such ingredient conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per milliliter and moisture.

(ii) The penicillin G used in making the batch; potency, toxicity, pH, moisture, crystallinity, and the penicillin G content.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 or more than 12 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The penicillin G used in making the batch; 10 packages, each containing approximately equal portions of not less than 60 milligrams, packaged in accordance with the requirements of § 146a.24 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch; 1 package of each containing approximately 5.0 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i), (ii), and (iii) of this section.

(2) If the Commissioner considers that investigations, other than the examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.29 *Penicillin with aluminum hydroxide gel*—(a) *Standards of identity, strength, quality, and purity.* Penicillin with aluminum hydroxide gel is a packaged combination of one immediate container of penicillin and one immediate container of aluminum hydroxide gel. Such penicillin conforms to the standards prescribed therefor by § 146a.24 (a), except subparagraphs (1) and (4) of § 146a.24 (a), but its potency is not less than 300 units per milligram. Such aluminum hydroxide gel conforms to the standards prescribed therefor by the U. S. P., but contains not more than 50 viable microorganisms per milliliter.

(b) *Packaging.* The immediate container of the penicillin shall conform to the packaging requirements set forth in § 146a. 24 (b), except that it shall contain not less than 300,000 units and its closure may be one through which a hypodermic needle cannot be introduced. The immediate container of the aluminum hydroxide gel shall be a tight container as defined by the U. S. P.; the quantity therein shall be 30 milliliters for each 100,000 units in the immediate container of penicillin.

(c) *Labeling.* Each package of penicillin with aluminum hydroxide gel shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and on the immediate container of the penicillin:

(i) The batch mark;

(ii) The number of units in such container; and

(iii) The statement "Expiration date --------", the blank being filled in with the date which is 18 months after the month during which the batch was certified, unless it is crystalline penicillin, in which case the blank is filled in with the date which is 36 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the immediate container of the penicillin, the statement "Warning—Not for injection," unless it conforms to the standards and packaging requirements prescribed therefor by § 146a.24 (a) and (b), except that the immediate container may contain 300,000 units.

(3) On the immediate container of the aluminum hydroxide gel, the conditions under which the mixture should be stored, including a reference to its instability when stored under other conditions, and the statement "The mixture may be kept in refrigerator for 1 week without significant loss of potency," unless such information is contained in the circular or other labeling within or attached to the package.

(4) On the outside wrapper or container and the immediate container of the aluminum hydroxide gel:

(i) A statement giving the method for dissolving the penicillin in the aluminum hydroxide gel.

(ii) The potency per milliliter after the penicillin has been dissolved therein.

(5) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is not crystalline penicillin,, the statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)."

(iii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(6) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Requests for certification; samples.* (1) In addition to complying with requirements of § 146.2 of this chapter, a person who requests certification of a batch of penicillin for inclusion in such combination shall submit with his request a statement showing the batch mark of the penicillin, the number of packages thereof in such batch, the number of units in the immediate container thereof, and (unless it was previously submitted) the date on which the latest assay of the penicillin included in such combination was completed, and a statement that the aluminum hydroxide gel conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph such person shall submit in connection with his request results of the tests and assays made by him on an accurately representative sample of the penicillin for potency, sterility, toxicity, moisture, pH, penicillin K content (unless it is crystalline penicillin G), crystallinity and heat stability if it is crystalline penicillin, and the penicillin G content if it is crystalline penicillin G.

(3) If the penicillin has not been certified previously, such person shall submit in connection with his request a sample of the batch consisting of one package for each 5,000 packages in the batch, but in no case less than 6 or more than 13 packages except that in the case of crystalline penicillin other than crystalline penicillin G such sample shall consist of not less than 8 and not more than 15 packages, and in the case of crystalline penicillin G not less than 10 and not more than 17 packages. Such sample shall be collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(4) No result referred to in subparagraph (2) of this paragraph is required if such result has been previously submitted.

(e) *Fees.* The fees for the services rendered with respect to each batch of penicillin for inclusion in combination with aluminum hydroxide gel under the regulations in this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) (3) of this section, or $2.00 if no such sample is submitted, and

(2) If the Commissioner considers that investigations, other than examination of such containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.30 *Penicillin troches* — (a) *Standards of identity, strength, quality, and purity.* Penicillin troches are troches composed of sodium penicillin, calcium penicillin, potassium penicillin, procaine penicillin, *l*-ephenamine penicillin G, or crystalline penicillin O and one or more suitable or harmless diluents, binders, and lubricants, with or without one or more suitable and harmless local anesthetics, chemical antimicrobial agents, masticatory substances, colorings, and flavorings. The potency of each troche is not less than 500 units; the moisture content is not more than 1.0 percent, except that if flavorings are omitted and it contains crystalline penicillin in a base of not less than 50 percent gelatin by weight, its moisture content is not more than 2 percent. The sodium penicillin, calcium penicillin, crystalline penicillin O, or potassium penicillin used conforms to the requirements of § 146a.24 (a) except the limitation on penicillin K content and except subparagraphs (1), (2), and (4) of § 146a.24 (a), but the potency is not less than 300 units per milligram. The procaine penicillin used conforms to the requirements of § 146a.44 (a), except the limitation on penicillin K content and except subparagraphs (2) and (3) of § 146a.44 (a). The *l*-ephenamine penicillin G used conforms to the requirements of § 146a.64 (a), except subparagraphs (2) and (3) of that paragraph. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each penicillin troche is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the troches by a plug of cotton or other like material. The composition of the immediate container, or foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of penicillin troches shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units of penicillin, and if it contains a local anesthetic or a chemical antimocrobial agent the quantity of each in each troche of the batch; and

(iii) The statement "Expiration date ____________," the blank being filled in, if crystalline penicillin, procaine penicillin, *l*-ephenamine penicillin G, or crystalline penicillin O is not used, with the date which is 9 months; or if crystalline penicillin, procaine penicillin, *l*-ephenamine penicillin G, or crystalline penicillin O is used, with the date which is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 18 months or 24 months or 36 months or 48 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) If crystalline penicillin, procaine penicillin, *l*-ephenamine penicillin G, or crystalline penicillin O is not used, the statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)";

(ii) The statement "Caution: Federal law prohibits dispensing without prescription";

(iii) If it is packaged for dispensing, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the label and labeling, whereever the name penicillin troches appears:

(i) Immediately preceding such name, if a masticatory substance is present, the word "chewing" or "masticatory"; and

(ii) Immediately following such name, if a local anesthetic and/or a chemical antimicrobial agent is present, the words "with ____________," the blank being filled in with the common or usual name of each such other ingredient present.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of penicillin troches shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each troche, the quantity of each ingredient used in making the batch, the date on which the latest assay of the troches comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per troche, average moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH; crystallinity if it is crystalline penicillin; specific rotation if it is *l*-ephenamine penicillin G; heat stability if it is crystalline sodium penicillin, potassium penicillin, *l*-ephenamine penicillin G, or crystalline penicillin O; the penicillin G content if it is crystalline sodium penicillin G, potassium penicillin G, or crystalline penicillin O; the procaine penicillin G content if it is crystalline procaine penicillin G; the *l*-ephenamine penicillin G content if it is *l*-ephenamine penicillin G, and the penicillin O content if it is crystalline penicillin O.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one troche for each 5,000 troches in the batch, but in no case less than 20 troches or more than 100 troches, collected by taking single troches at such intervals throughout the entire time the troches are being made that the quantities made during the intervals are approximately equal.

(ii) The penicillin used in making the batch; 5 packages, or in the case of crystalline penicillin 10 packages, each containing approximately equal portions of not less than 60 milligrams if it is not procaine penicillin or *l*-ephenamine penicillin G, and not less than 300 milligrams if it is procaine penicillin or *l*-ephenamine penicillin G, packaged in accordance with the requirements of § 146a.24 (b), § 146a.44 (b), or § 146a.64 (b).

(iii) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the service rendered with respect to each batch of penicillin troches under the regulations in this part shall be:

(1) $1.00 for each troche without masticatory substance in the sample submitted in accordance with paragraph (d) (3) (i) of this section, $2.00 for each troche with masticatory substance in such sample. $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such troches, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

(f) *Exemption of penicillin troches from certification.* Penicillin troches that conform to the requirements of paragraphs (a), (b), and (c) of this section, except paragraph (c) (1) (iii) of this section, shall be exempt (unless they contain crystalline penicillin O or *l*-ephenamine penicillin) from the requirements of sections 502 (l) and 507 of the act, if they comply with the following conditions:

(1) The outside wrapper or container and the immediate container bear an expiration date not more than 48 months after the month during which the batch was last assayed and released by the manufacturer; and

(2) The brochure, printed matter, and circular referred to in paragraph (c) (2) (iii) of this section bear information that the drug is for use only as a local treatment for Vincent's infection (Vincent's angina) and as an adjunct in pericoronitis and other superficial dental infections due to penicillin-sensitive organisms; and further, that such brochure, printed matter, and circular bear directions and warnings adequate for such use by practitioners licensed by law to administer such drug.

§ 146a.31 *Penicillin dental cones (calcium penicillin dental cones, penicillin dental cones calcium salt, crystalline penicillin dental cones)*—(a) *Standards of identity, strength, quality, and purity.* Penicillin dental cones are composed of calcium penicillin or crystalline penicillin and one or more suitable and harmless diluents, binders, and lubricants, with or without a suitable local anesthetic and with or without one or more suitable sulfonamides. The potency of each cone is not less than 500 units. Its moisture content is not more than 1.0 percent. If a sulfonamide is used its quantity is not less than 0.032 gram per cone. The penicillin used conforms to the requirements of § 146a.24 (a) except the limitation on penicillin K content and except subparagraphs (1), (2), and (4) of § 146a.24 (a), but its potency is not less than 300 units per milligram. Each other ingredient used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each penicillin dental cone is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the cones by a plug of cotton or other like material. The composition of the immediate container, or foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of penicillin dental cones shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in each cone of the batch;

(iii) If the batch contains, in addition to penicillin, one or more other active ingredients specified in paragraph (a) of this section, the name and quantity of each such other ingredient in each cone;

(iv) The statement "Expiration date ____________," the blank being filled in, if crystalline penicillin is used, with the date which is 36 months, or if crystalline penicillin is not used, with the date which is 12 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the label and labeling, if it contains, in addition to penicillin, one or more other active ingredients specified in paragraph (a) of this section, after the name "penicillin dental cones," wherever it appears, the words "with ______" in juxtaposition with such name, the blank being filled in with the common or usual name of each such other ingredient used.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of penicillin dental cones shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each cone, the quantity of each ingredient used in making the batch, the date on which the latest assay of the cones comprising such batch was completed, and that each other ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following made by him on an accurately representative sample of:

(i) The batch; average potency per cone and average moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, crystallinity, and heat stability if it is crystalline penicillin and the penicillin G content if it is crystalline penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one cone for each 5,000 cones in the batch, but in no case less than 20 cones or more than 100 cones, collected by taking single cones at such intervals throughout the entire time the cones are being made that the quantities made during the intervals are approximately equal.

(ii) The penicillin used in making the batch; five packages if it is calcium penicillin or 10 packages if it is crystalline penicillin containing approximately equal portions of not less than 60 milligrams each, packaged in accordance with the requirements of § 146a.24 (b).

(iii) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin dental cones under the regulations in this part shall be:

(1) $1.00 for each cone in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such cones and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.32 *Penicillin with vasoconstrictor; penicillin with ______________ (the blank being filled in with the common or usual name of the vasoconstrictor)*—(a) *Standards of identity, strength, quality, and purity.* Penicillin with vasoconstrictor is a dry mixture of penicillin and a suitable vasoconstrictor with or without suitable buffer substances and preservatives, or it is a packaged combination of one immediate container of penicillin and one immediate container of an aqueous solution of a suitable vasoconstrictor. The penicillin is of such quantity that when dissolved as directed the potency of such solution is not less than 500 units per milliliter after it has been kept for 7 days at a temperature of 15° C. (59° F.). Such solution is isotonic and has a pH of 6, ±0.2. The moisture content of the dry mixture of penicillin with vasoconstrictor is not more than 1.5 percent. The penicillin used conforms to the requirements of § 146a.24 (a), except the limitation on penicillin K content and except subparagraphs (2) and (4) of that paragraph. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Each immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The immediate container of the dry mixture of penicillin with vasoconstrictor may be packaged in combination with an immediate container of a suitable aqueous diluent.

(c) *Labeling.* Each package of penicillin with vasoconstrictor shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and on the immediate container of the penicillin:

(i) The batch mark;

(ii) The number of units in such container; and

(iii) If it is a packaged combination of one immediate container of penicillin and one immediate container of a vasoconstrictor, the statement "Expiration date ____________," the blank being filled in with the date which is 18 months, or if it is crystalline penicillin 36 months, after the month during which the batch was certified. If it is the dry mixture of penicillin with vasoconstrictor, the statement "Expiration date ______," the blank being filled in with the date which is 24 months after the month during which the batch was certified. Such expiration dates may be omitted from the immediate container if such container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container and on the immediate container of the solution in the packaged combination:

(i) A statement giving the method of dissolving the penicillin, and if it is not a packaged combination, a statement that distilled water U. S. P. should be used;

(ii) The potency per milliliter after the penicillin has been dissolved therein;

(iii) If it is a packaged combination of one immediate container of penicillin and one immediate container of a vasoconstrictor and it is not crystalline penicillin, the statement "Store in refrigerator not above 15° C. (59° F.)";

(iv) The statement "Warning—Not for injection";

(v) The conditions under which the solution should be stored, including a reference to its instability when stored under other conditions, and a statement "The solution may be kept in a refrigerator for one week without significant loss of potency."

(3) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter a person who requests certification of a batch of penicillin with vasoconstrictor shall submit with his request a statement showing the batch mark, the number of packages thereof in such batch, the number of units in each immediate container thereof, and (unless it was previously submitted) the date on which the latest assay of the penicillin included in such batch was completed, the quantity of each ingredient used in making the batch of the dry mixture of penicillin with vasoconstrictor, the quantity of each ingredient used in making the solution included in the packaged combination, and a statement that such solution conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The penicillin included in the packaged combination and the penicillin used in making the batch of the dry mixture of penicillin with vasoconstrictor; potency, toxicity, moisture, pH, crystallinity and heat stability, if it is crystalline penicillin, and the penicillin G content if it is crystalline penicillin G.

(ii) The solution after the penicillin has been dissolved therein; potency.

(iii) The batch of the dry mixture of penicillin with vasoconstrictor; potency, moisture content.

(3) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) If it contains only penicillin and the penicillin used has been previously submitted, or it contains penicillin and other ingredients; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 or more than 12 immediate containers, unless it is in tablet form in which case such sample shall consist of not less than 20 nor more than 100 tablets.

(*b*) If it contains only penicillin and the penicillin used has not been previously submitted; one immediate container or tablet for each 5,000 immediate containers or tablets, but in no case less than 40 immediate containers or tablets and not more than 100 immediate containers or tablets.

Such sample shall be collected by taking single immediate containers or tablets at such intervals throughout the entire time of packaging or tableting the batch that the quantities packaged or tableted during the intervals are approximately equal.

(ii) The penicillin used in making the batch of the dry mixture of penicillin with vasoconstrictor; 5 packages, or in the case of crystalline penicillin 10 packages, each containing approximately equal portions of not less than 60 milligrams each, packaged in accordance with the requirements of § 146a.24 (b).

(iii) In case of an initial request for certification of a batch of a dry mixture of penicillin with vasoconstrictor, each other substance used in making the batch; one package of each containing approximately 5 grams.

(iv) In case of an initial request for certification of the packaged combination of penicillin with vasoconstrictor, or when any change is made in the composition of such solution; five packages of the solution included in the combination.

(4) No result referred to in subparagraph (2) (i) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, are required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin with vasoconstrictor under the regulations in this part shall be:

(1) $1.00 for each tablet submitted in accordance with paragraph (d) (3) (i) (*a*) and (*b*) of this section; $1.00 for each immediate container submitted in accordance with paragraph (d) (3) (i) (*b*) of this section; and $4.00 for each immediate container submitted in accordance with paragraph (d) (3) (i) (*a*), (ii), (iii), and (iv) of this section.

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.33 *Penicillin for surface application*—(a) *Standards of identity, strength, quality, and purity.* Penicillin for surface application is calcium penicillin and one or more of the diluents sodium chloride, milk sugar, sodium citrate, and dextrose. Its moisture content is not more than 1.0 percent. The penicillin used conforms to the requirements of § 146a.24 (a), except the limitation of penicillin K content and except subparagraphs (1), (2), and (4) of § 146a.24 (a), but its potency is not less than 300 units per milligram. Each diluent conforms to the standards prescribed therefor by the U. S. P.

(b) *Packaging.* Unless the penicillin for surface application is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each immediate container (except when its content is two or more foil or film enclosures) and each foil or film enclosure shall contain not less than 10,000 units or more than 50,000 units and shall be so sealed that the contents cannot be used without destroying such seal.

(c) *Labeling.* Each package of penicillin for surface application shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in the immediate container or in each foil or film enclosure therein, and the number of such foil or film enclosures;

(iii) The statement "Expiration date ----," the blank being filled in with the date which is 12 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(iv) In case the drug is not sterile, the statement "Not sterile—not for injection—not to be used in deep wounds or body cavities."

(2) On the immediate container, the conditions under which solutions of penicillin for surface application should be stored, including a reference to their instability when stored under other conditions, and the statement "The mixture may be kept in refrigerator for 1 week without significant loss of potency," unless such information is contained in the circular or other labeling within or attached to the package.

(3) On the outside wrapper or container:

(i) The statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)."

(ii) If two or more immediate containers or foil or film enclosures are in such packages, the number of such containers or foil or film enclosures therein and the number of units in each.

(iii) The statment "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(iv) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of penicillin for surface application shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each immediate container or foil or film enclosure, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that the sodium chloride, milk sugar, sodium citrate, and dextrose used in making such batch conform to the standards prescribed therefor by the U. S. P.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per immediate container or foil or film enclosure, moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container or, if the drug is packed in foil or film enclosures, one such enclosure for each 5,000 such containers or enclosures in the batch, but in no case less than 20 such containers or enclosures or more than 100, collected by taking single containers or enclosures at such intervals throughout the entire time of packaging the batch, that the quantities packed during the intervals are approximately equal.

(ii) The penicillin used in making the batch; five packages containing approximately equal portions of not less than 60 milligrams each, packaged in accordance with the requirements of § 146a.24 (b).

(iii) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin for surface application under the regulations in this part shall be:

(1) $1.00 for each immediate container or foil or film enclosure, whichever is the greatest number, in the samples submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such containers or enclosures, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter, for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.34 *Tablets aluminum penicillin*—(a) *Standards of identity, strength, quality, and purity.* Tablets aluminum penicillin are tablets composed of aluminum penicillin and sodium benzoate, with or without one or more suitable and harmless diluents, binders, lubricants, colorings, and flavorings. The potency of each tablet is not less than 50,000 units, and if it is less than 100,000 units it is "unscored". Each tablet contains 0.3 gram of sodium benzoate. Its moisture content is not more than 2 percent. The aluminum penicillin used conforms to the requirements of § 146a.42 (a) for aluminum penicillin except subparagraphs (2) and (3) thereof. Each other substance used in the preparation of aluminum penicillin tablets, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each tablet aluminum penicillin is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the tablets by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The number of tablets in the immediate container is such that the total number of units therein is not less than 300,000.

(c) *Labeling.* Each package of tablets aluminum penicillin shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in each tablet of the batch;

(iii) The quantity of sodium benzoate in each tablet;

(iv) The statement "Expiration date -------------," the blank being filled in with the date which is 24 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) The statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)."

(ii) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and is intended solely for veterinary use and is conspicuously so labeled.

(iii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification, samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of tablets aluminum penicillin shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each tablet; the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per tablet, average moisture.

(ii) The aluminum penicillin used in making the batch; potency, moisture, pH, toxicity, and penicillin K content.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one tablet for each 5,000 tablets in the batch, but in no case less than 20 tablets or more than 100 tablets, collected by taking single tablets at such intervals throughout the entire time of tableting that the quantities tableted during the intervals are approximately equal.

(ii) The aluminum penicillin used in making the batch; 6 packages, each containing approximately equal portions of not less than 300 milligrams each, packaged in accordance with the requirements of § 146a.42 (b).

(iii) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately five grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of tablets aluminum penicillin under this part shall be:

(1) $1.00 for each tablet in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii), of this section; and

(2) If the Commissioner considers that investigations, other than examination of such tablets and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter, for the issuance of a certificate, the costs of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.35 *Penicillin sulfonamide powder (calcium penicillin sulfonamide powder, crystalline penicillin sulfonamide powder)*—(a) *Standards of identity, strength, quality, and purity.* Penicillin sulfonamide powder is composed of calcium penicillin or crystalline penicillin and one or both of the sulfonamides, sulfanilamide and sulfathiazole. It is sterile. Its moisture content is not more than 1.0 percent. The quantity of each sulfonamide used is not more than 0.05 gram for each 100 units of penicillin used. The penicillin used conforms to the requirements of § 146a.24 (a) except limitation on penicillin K content and except subparagraphs (1) and (4) of § 146a.24 (a), but its potency is not less than 300 units per milligram. Each sulfonamide used conforms to the standards prescribed therefor by the U. S. P.

(b) *Packaging.* In all cases, the immediate container of penicillin sulfonamide powder shall be a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, shall be sterile at the time of filling and closing, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. If the penicillin sulfonamide powder is packaged for "dusting" purposes each package shall contain not less than 5,000 units of penicillin. If the penicillin sulfonamide powder is packaged for dental use it shall be packaged in immediate containers of colorless, transparent glass meeting the test for glass containers of type I or type II prescribed by the U. S. P. The glass containers shall be open at both ends, one of which is constricted, both ends shall be capable of closure with rubber stoppers, and each such container shall contain not less than 500 units of penicillin. Each package of penicillin sulfonamide powder for dental use shall contain a suitable device for insufflation purposes.

(c) *Labeling.* Each package of penicillin sulfonamide powder shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and immediate container:

(i) The batch mark.

(ii) The number of units in each immediate container.

(iii) The statement "Expiration date ________," the blank being filled in, if crystalline penicillin is used, with the date which is 24 months, or if crystalline penicillin is not used, with the date which is 9 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(iv) If crystalline penicillin is not used, the statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)."

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the label and the labeling, after the name penicillin sulfonamide powder, wherever it appears, the words "with ______________" in juxtaposition with such name, the blank being filled in with the name of the sulfonamide used.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of penicillin sulfonamide powder shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each container of penicillin sulfonamide powder, the quantity of each ingredient used in making the batch, the date on which the latest assay of the penicillin sulfonamide powder comprising such batch was completed, and that such sulfonamide used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per container, average moisture, sterility.

(ii) The penicillin used in making the batch; potency, sterility, toxicity, moisture, pH, crystallinity and heat stability if it is crystalline penicillin and the penicillin G content if it is crystalline penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility: one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 or more than 12 immediate containers, unless each such container is packaged to contain more than 1 gram, in which case the sample shall consist of 1 gram for each 5,000 immediate containers in the batch, but in no case less than 5 grams or more than 12 grams.

(*b*) For sterility testing; 10 immediate containers.

Such samples shall be collected by taking single immediate containers or 1-gram portions at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The penicillin used in making the batch:

(*a*) For all tests except sterility; 5 packages, or in the case of crystalline penicillin 10 packages, each containing approximately equal portions of not less than 60 milligrams.

(*b*) For sterility testing; 10 packages, each containing approximately equal portions of not less than 300 milligrams. Such samples shall be packaged in accordance with the requirements of § 146a.24 (b).

(iii) In case of an initial request for certification, each sulfonamide used in making the batch; one package of each containing approximately five grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin sulfonamide powder under the regulation in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (3) (i) (*a*), (ii) (*a*), and (iii) of this section.

(2) If the Commissioner considers that investigations, other than examination of such penicillin sulfonamide powder and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.36 *Penicillin vaginal suppositories*—(a) *Standards of identity, strength, quality, and purity.* Penicillin vaginal suppositories are suppositories composed of sodium penicillin, calcium penicillin, potassium penicillin, or procaine penicillin in a base of spermaceti and cocoa butter. The potency of each suppository is not less than 100,000 units; its moisture content is not more than 1.0 percent. The sodium penicillin, calcium penicillin, and potassium penicillin used conform to the requirements of § 146a.24 (a), except subparagraphs (1), (2), and (4) of that paragraph, but its potency is not less than 300 units per milligram. The procaine penicillin used conforms to the requirements of § 146a.44 (a), except subparagraphs (2) and (3) of that paragraph. The spermaceti and cocoa butter used conform to the standards prescribed therefor by the U. S. P.

(b) *Packaging.* In all cases, the immediate container of penicillin vaginal suppositories shall be a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of penicillin vaginal suppositories shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in each suppository of the batch; and

(iii) The statement "Expiration date ________________," the blank being filled in with the date which is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 18 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) The statement "Store in refrigerator not above 15° C. (59° F.)," or "Store below 15° C. (59° F.)";

(ii) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled;

(iii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of penicillin vaginal suppositories shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each suppository, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that the spermaceti and cocoa butter used in making such batch conform to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per suppository, and moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, penicillin K content (unless it is crystalline sodium, potassium, or procaine penicillin G), crystallinity if it is crystalline penicillin, heat stability if it is crystalline sodium or potassium penicillin, the penicillin G content if it is crystalline sodium or potassium penicillin G, and the procaine penicillin G content if it is procaine penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph such person shall submit in connection with his request in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one suppository for each 5,000 suppositories in the batch, but in no case less than 20 suppositories or more than 100 suppositories, collected by taking single suppositories at such intervals throughout the entire time the suppositories are being made, that the quantities made during the intervals are approximately equal.

(ii) The penicillin used in making the batch; 6 packages, or in the case of crystalline penicillin 10 packages, each containing approximately equal portions of not less than 60 milligrams if it is not procaine penicillin, and not less than 300 milligrams, if it is procaine penicillin, packaged in accordance with the requirements of § 146a.24 (b) or § 146a.44 (b).

(iii) In case of an initial request for certification, the spermaceti and cocoa butter used in making the batch; one package of each containing, respectively, approximately 10 grams and 100 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin vaginal suppositories under the regulations in this part shall be:

(1) $1.00 for each suppository in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations other than examination of such suppositories and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.37 *Buffered crystalline penicillin.* Buffered crystalline penicillin conforms to all requirements prescribed by § 146a.24 for crystalline penicillin, and is subject to all procedures prescribed by § 146a.24 for crystalline penicillin, except that:

(a) It contains the buffer sodium citrate in a quantity not less than 4.0 percent and not more than 5.0 percent by weight of its total solids; such sodium citrate conforms to the standards prescribed therefor by the U. S. P.;

(b) If it is crystalline penicillin G, the penicillin G content is corrected for the sodium citrate content;

(c) The immediate container, if it is packaged for dispensing, shall bear, in lieu of the statement prescribed for crystalline penicillin by § 146a.24 (c) (2), the statement "Sterile solution may be kept in refrigerator for 1 week without significant loss of potency," unless such information is contained in the circular or other labeling within or attached to the package from which it is dispensed;

(d) A person who requests certification of a batch shall submit with his request a statement showing the quantity of sodium citrate used in making the batch, that such sodium citrate conforms to the requirements prescribed therefor by this section, and in case of an initial request for certification he shall submit an accurately representative sample of such sodium citrate consisting of approximately 5 grams; and

(e) The fee for the services rendered with respect to the sample of sodium citrate submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

(f) Exemption of buffered crystalline penicillin G from certification: Buffered crystalline penicillin G that conforms to the requirements of this section shall be exempt from the requirements of sections 502 (l) and 507 of the act, if it complies with the following conditions:

(1) The outside wrapper or container and the immediate container bear an expiration date not more than 36 months after the month during which the batch was last assayed and released by the manufacturer; and

(2) It is intended for use by man and the brochure, printed matter, and the circular referred to in § 146a.24 (c) (3) (iii) bear information that the drug is for use only in the treatment of the following conditions; and further, that such brochure, printed matter, and circular bear directions and warnings adequate for such uses by practitioners licensed by law to administer such drug:

(i) Staphylococcic infections with and without bacteremia.

(ii) Hemolytic streptococcic infections including bacteremia.

(iii) Anaerobic streptococcic infections.

(iv) Pneumococcic infections.

(v) Gonococcic infections.

(vi) Syphilis.

(vii) Anthrax.

(viii) As an adjunct to specific antitoxin therapy for clostridial infections.

(ix) Bacterial endocarditis due to penicillin-sensitive organisms.

(x) Diphtheria, with antitoxin therapy.

(xi) Pulmonary suppuration due to penicillin-sensitive organisms.

(xii) Vincent's infection.

(xiii) Erysipeloid (swine erysipelas).

(xiv) Meningococcic infections.

(xv) For the prevention of possible secondary infection following tonsillectomy and tooth extraction in patients with a history of rheumatic fever or rheumatic heart disease, in congenital heart disease, and in other conditions in which secondary infection may occur; or

(3) It is intended solely for veterinary use and is conspicuously so labeled, and its labeling bears information that the

drug is for use only in the treatment of one or more of the following conditions, and further, bears directions and warnings adequate for such use:

(i) Bovine mastitis caused by Streptococcus agalactiae.
(ii) Leptospirosis in dogs.
(iii) Osteomyelitis.
(iv) Peritonitis.
(v) Strangles of horses.
(vi) Equine pneumonia.
(vii) Early tetanus, with antitoxin therapy.
(viii) Calf pneumonia.
(ix) Calf diphtheria.
(x) Pyelonephritis in cattle.
(xi) Blackleg.
(xii) Malignant edema.
(xiii) Early anthrax.
(xiv) Metritis.
(xv) Bovine actinomycosis.
(xvi) Swine erysipelas in turkeys.

If such drug is represented for use as a treatment for mastitis, its labeling shall bear the statement, "Important: Milk from treated segments of udders should be discarded or used for purposes other than human consumption for at least 72 hours after the last treatment."

§ 146a.38 *Capsules buffered penicillin with pectin hydrolysate (capsules buffered potassium penicillin with pectin hydrolysate)* — (a) *Standards of identity, strength, quality and purity.* Capsules buffered penicillin with pectin hydrolysate are capsules composed of potassium penicillin with pectin hydrolysate and sodium citrate enclosed in a hard gelatin capsule. The potassium penicillin with pectin hydrolysate is prepared by lyophilizing a solution containing one part potassium penicillin and three parts of pectin hydrolysate by weight. The potency of each capsule is not less than 50,000 units. Its moisture content is not more than 4.0 percent. The penicillin used conforms to the requirements prescribed by § 146a.24 (a) for potassium penicillin except § 146a.24 (a), (2) and (4). The pectin hydrolysate is obtained by mild hydrolysis of pectin with sodium hydroxide and hydrochloric acid. It is a free flowing and opalescent solution light tan to beige in color and is precipitated by the lower alcohols and ketones. Its pH is 6.0 to 7.0. It is substantially free of any turbidity or undissolved material. The pectin used conforms to the standards prescribed by the N. F. The sodium citrate and the sodium hydroxide and hydrochloric acid used in the preparation of the pectin hydrolysate conform to the standards prescribed therefor by the U. S. P.

(b) *Packaging.* Unless each capsule of buffered penicillin with pectin hydrolysate is enclosed in foil or plastic film and such enclosure complies with the definition of a tight container as prescribed by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the capsules by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The number of capsules in the immediate container is such that the total number of units therein is not less than 300,000.

(c) *Labeling.* Each package of capsules buffered penicillin with pectin hydrolysate shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in each capsule of the batch;

(iii) The quantity of the sodium citrate in each capsule of the batch; and

(iv) The statement "Expiration date --------," the blank being filled in with the date which is twelve months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of capsules buffered penicillin with pectin hydrolysate shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each capsule, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per capsule, average moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, penicillin K content (unless it is crystalline penicillin G), crystallinity, and heat stability, and if it is crystalline penicillin G, penicillin G content.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one capsule for each 5,000 capsules in the batch, but in no case less than 20 capsules or more than 100 capsules, collected by taking single capsules at such intervals throughout the entire time of capsuling that the quantities capsuled during the intervals are approximately equal.

(ii) The penicillin used in making the batch; ten packages containing approximately equal portions of not less than 60 milligrams each, packaged in accordance with the requirements of § 146a.24 (b).

(iii) In case of an initial request for certification, one package of approximately 250 cc. of the pectin hydrolysate and one package of approximately five grams of the sodium citrate used in making the batch, one package of approximately 50 cc. of the hydrochloric acid, and one package of approximately five grams of the sodium hydroxide used in preparing the pectin hydrolysate.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or such sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of capsules buffered penicillin with pectin hydrolysate under the regulations in this part shall be:

(1) $1.50 for each capsule in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the sample submitted in accordance with paragraph (d) (3) (ii) and (iii), of this section; and

(2) If the Commissioner considers that investigations, other than examination of such capsules and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.39 *Capsules procaine penicillin in oil*—(a) *Standards of identity; strength, quality, and purity.* Capsules procaine penicillin in oil are capsules composed of procaine penicillin, aluminum monostearate, and sesame oil or peanut oil, enclosed in a suitable and harmless soft gelatin capsule. The potency of each capsule is not less than 200,000 units. Its moisture content is not more than 2.5 percent. The procaine penicillin used conforms to the standards prescribed by § 146a.44 (a) except § 146a.44 (a) (2) and (3). Each other ingredient used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of units in each capsule of the batch.

(iii) The name of the vegetable oil and the quantity of aluminum monostearate used in making the batch.

(iv) The statement "Expiration date --------," the blank being filled in with the date which is 36 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each capsule, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per capsule and average moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, penicillin K content (unless it is procaine penicillin G), crystallinity, and the procaine penicillin G content.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; 1 capsule for each 5,000 capsules in the batch, but in no case less than 20 capsules or more than 100 capsules, collected by taking single capsules at such intervals throughout the entire time of capsuling the batch that the quantities capsuled during the intervals are approximately equal.

(ii) The penicillin used in making the batch; 10 packages each containing approximately equal portions of not less than 300 milligrams, packaged in accordance with the requirements of § 146a.44 (b).

(iii) In case of an initial request for certification, the sesame oil or peanut oil and each other ingredient used in making the batch; 1 package of each containing, respectively, approximately 250 grams and approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $1.00 for each capsule in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section.

(2) If the Commissioner considers that investigations other than examination of such capsules and packages are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.40 *Penicillin bougies (sodium penicillin bougies, calcium penicillin bougies, potassium penicillin bougies, procaine penicillin bougies, penicillin bougies sodium salt, penicillin bougies calcium salt, penicillin bougies potassium salt, penicillin bougies procaine salt)*—(a) *Standards of identity, strength, quality, and purity.* Penicillin bougies are bougies composed of sodium penicillin, calcium penicillin, potassium penicillin, or procaine penicillin in an excipient of polyethylene glycol or of one or more other suitable and harmless diluents, binders, and lubricants. The potency of each bougie is not less than 25,000 units. Its moisture content is not more than 1.0 percent, except if it contains procaine penicillin, its moisture content is not more than 2.0 percent. The sodium penicillin, calcium penicillin, or potassium penicillin used conforms to the requirements of § 146a.24 (a), except the limitation on penicillin K content and except § 146a.24 (a) (1), (2), and (4), but its potency is not less than 300 units per milligram. The procaine penicillin used conforms to the requirements of § 146a.44 (a), except the limitation on penicillin K content and except § 146a.44 (a) (2) and (3). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each penicillin bougie is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the bougies by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of penicillin bougies shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in each bougie of the batch;

(iii) The statement "Expiration date ------------," the blank being filled in, if crystalline penicillin or procaine penicillin is used without the addition of an excipient of polyethylene glycol, with the date which is 36 months; or if crystalline penicillin or procaine penicillin is used with the addition of an excipient of polyethylene glycol, with the date which is 18 months, or if crystalline penicillin or procaine penicillin is not used, with the date which is 12 months after the month during which the batch was certified: *Provided, however*, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) If the excipient is polyethylene glycol, the statement "Store in refrigerator not above 15° C. (59° F.)", unless the person who requests certification has submitted to the Commissioner results of tests and assays showing that his drug is stable at room temperature;

(v) The statement "For veterinary use only."

(2) On the circular or other labeling within or attached to the package, if it is packaged for dispensing, adequate directions and warnings for the veterinary use of such drug by the laity.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of penicillin bougies shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each bougie, the quantity of each ingredient used in making the batch, and the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per bougie, and moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, crystallinity, and heat stability if it is crystalline sodium or potassium penicillin, the penicillin G content if it is crystalline sodium or potassium penicillin G, and the procaine penicillin G content if it is crystalline procaine penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one bougie for each 5,000 bougies in the batch, but in no case less than 20 bougies or more than 100 bougies, collected by taking single bougies at such intervals throughout the entire time the bougies are being made, that the quantities made during the intervals are approximately equal.

(ii) The penicillin used in making the batch; 5 packages, or in the case of crystalline penicillin 10 packages, each containing approximately equal portions of not less than 60 milligrams if it is not procaine penicillin and not less than 300 milligrams if it is procaine penicillin, packaged in accordance with the requirements of § 146a.24 (b) or § 146a.44 (b).

(iii) In case of an initial request for certification, each polyethylene glycol and each other ingredient used in making the batch; one package of each containing approximately 25 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin bougies under the regulations in this part shall be:

(1) $1.00 for each bougie in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations other than examination of such bougies and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.41 *Crystalline penicillin and epinephrine in oil*—(a) *Standards of identity, strength, quality, and purity.* Crystalline penicillin and epinephrine in oil is a suspension of crystalline penicillin and epinephrine in a menstruum of refined peanut oil or sesame oil. Each milliliter has a potency of 300,000 units and contains 0.3 milligram of epinephrine. Its moisture content is not more than 0.2 percent. It is sterile. The penicillin used conforms to the requirements of § 146a.24 (a) for crystalline penicillin. The epinephrine, peanut oil, and sesame oil used conform to the standards prescribed therefor by the U. S. P.

(b) *Packaging.* The immediate container of crystalline penicillin and epinephrine in oil shall be of colorless transparent glass so closed as to be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that its contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The quantity of crystalline penicillin and epinephrine in oil in each such container shall be not less than one milliliter and not more than 20 milliliters unless it is packaged for repacking. Unless it is packaged for repacking each container shall be filled with a volume of crystalline penicillin and epinephrine in oil in excess of that designated, which excess shall be sufficient to permit the withdrawal and the administration of the volume indicated whether administered in either single or multiple doses.

(c) *Labeling.* Each package of crystalline penicillin and epinephrine in oil shall bear, on its label or labeling as hereinafter indicated the following:

(1) On the outside wrapper or container and the immediate container of the package:

(i) The batch mark;

(ii) The number of units per milliliter of the batch;

(iii) The quantity of epinephrine per milliliter of the batch;

(iv) The statement "Expiration date ------," the blank being filled in with the date which is 18 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(v) The statement "For intramuscular use only" and "Shake well"; and

(vi) The name of the oil used in making the batch.

(2) On the outside wrapper or container, the statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing:

(i) If it is intended for use by man, adequate directions and warnings for its use by practitioners licensed by law to administer such drug.

(ii) If it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of crystalline penicillin and epinephrine in oil shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each of such packages, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that the epinephrine, peanut oil or sesame oil used in making such batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, moisture and epinephrine content.

(ii) The penicillin used in making the batch; potency, sterility, toxicity, pyrogens, moisture, pH, penicillin K content (unless it is crystalline penicillin G), crystallinity, heat stability and the penicillin G content if it is crystalline penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility; one package for each 500 packages in the batch, but in no case less than 5 packages or more than 15 packages.

(*b*) For sterility testing; 10 packages.

Such samples shall be collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The penicillin used in making the batch:

(*a*) For all tests except sterility; 10 packages, each containing approximately equal portions of not less than 60 milligrams.

(*b*) For sterility testing; 10 packages, each containing approximately equal portions of not less than 300 milligrams.

Such samples shall be packaged in accordance with the requirements of § 146a.24 (b).

(iii) In case of an initial request for certification, the epinephrine and the peanut oil or sesame oil used in making the batch; one package of each containing approximately 2 grams and 250 grams, respectively.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of crystalline penicillin and epinephrine in oil under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (3) (i) (*a*), (ii) (*a*), and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examinations of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fees prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.42 *Aluminum penicillin (aluminum penicillin salt)*—(a) *Standards of identity, strength, quality, and purity.* Aluminum penicillin is the insoluble aluminum salt of a kind of penicillin or a mixture of two or more such salts, but the quantity of any salt of penicillin K therein is not more than 30 percent. Each such drug is so purified and dried that:

(1) Its potency is not less than 500 units per milligram;

(2) It is sterile;

(3) It is nonpyrogenic;

(4) It is nontoxic;

(5) Its moisture content is not more than 3 percent; and

(6) Its pH in saturated aqueous solution is not less than 3.5 and not more than 4.5.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of aluminum penicillin shall bear on its outside wrapper or container and the immediate container as hereinafter indicated, the following:

(1) The batch mark;

(2) The weight of the drug and the number of units in the immediate container;

(3) The statement "Expiration date ________", the blank being filled in with the date which is 12 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(4) The statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)";

(5) The statement "For manufacturing use only";

(6) The statement "Caution: Federal law prohibits dispensing without prescription."

(d) *Request for certification, check tests and assays; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of aluminum penicillin shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the weight of the drug and the number of units in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied or followed with results of the tests and assays made by him on the batch for potency, sterility, pyrogens, toxicity, moisture, pH, and the penicillin K content.

(2) Such person shall submit in connection with his request an accurately representative sample of the batch, consisting of the following:

(i) For all tests except sterility; 6 packages.

(ii) For sterility testing; 10 packages. Each such package shall contain approximately 300 milligrams taken from different parts of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(3) In connection with contemplated requests for certification of batches of another drug in the manufacture of which aluminum penicillin is to be used, the manufacturer of a batch which is to be so used may request the Commissioner to make check tests and assays on a sample of such batch taken as prescribed by subparagraph (2) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer results of each check test and assay as are so requested.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (2) (i) and (3) of this section; and

(2) If the Commissioner considers that investigations, other than the examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.43 *Aluminum penicillin in oil*—(a) *Standards of identity, strength, quality, and purity.* Aluminum penicillin in oil is a suspension of aluminum penicillin in a menstruum of refined peanut oil or sesame oil. Its potency is 300,000 units per milliliter. Its moisture content is not more than 1.5 percent. It is sterile. The aluminum penicillin used conforms to the requirements of § 146a.42 (a). The peanut oil or sesame oil used conforms to the standards prescribed therefor by the U. S. P.

(b) *Packaging.* The immediate container of aluminum penicillin in oil shall be of colorless, transparent glass, so closed as to be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that its contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The quantity of aluminum penicillin in oil in each such container shall be not less than 1 milliliter and not more than 20 milliliters, unless it is packaged for repacking. Unless it is packaged for repacking, each container shall be filled with a volume of aluminum penicillin in oil in excess of that designated, which excess shall be sufficient to permit the withdrawal and the administration of the volume indicated, whether administered in either single or multiple doses.

(c) *Labeling.* Each package of aluminum penicillin in oil shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside label or container and the immediate container of the package:

(i) The batch mark;

(ii) The number of units per milliliter of the batch;

(iii) The statement "Expiration date ------------," the blank being filled in with the date which is 12 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) The statements "For intramuscular use only" and "Shake well";

(v) The statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)"; and

(vi) The name of the oil used in making the batch.

(2) On the outside wrapper or container the statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing:

(i) If it is intended for use by man, adequate directions and warnings for its use by practitioners licensed by law to administer such drug.

(ii) If it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of aluminum penicillin in oil shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the aluminum penicillin used in making such batch was completed, the number of units in each of such packages, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that the peanut oil or sesame oil used in making such batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, moisture.

(ii) The aluminum penicillin used in making the batch; potency, sterility, toxicity, pyrogens, moisture, pH, penicillin K content.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility; one package for each 500 packages in the batch, but in no case less than 3 packages or more than 12 packages.

(*b*) For sterility testing; 10 packages.

Such samples shall be collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The aluminum penicillin used in making the batch:

(*a*) For all tests except sterility; 6 packages, each containing approximately equal portions of not less than 300 milligrams.

(*b*) For sterility testing: 10 packages, each containing approximately equal portions of not less than 300 milligrams.

Such samples shall be packaged in accordance with the requirements of § 146a.42 (b).

(iii) In case of an initial request for certification, the peanut oil or sesame oil used in making the batch; one package of each containing approximately 250 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of aluminum penicillin in oil under the regulations in this part shall be:

(1) $8.00 for each package in the sample submitted in accordance with paragraph (d) (3) (i) (*a*) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) (*a*) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than the examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.44 *Procaine penicillin (penicillin procaine salt), procaine penicillin G (penicillin G procaine salt)*—(a) *Standards of identity, strength, quality, and purity.* Procaine penicillin is the crystalline procaine salt of a kind of penicillin, or a mixture of two or more such salts prepared from procaine hydrochloride that compiles with all the standards prescribed by the U. S. P., except for the color of the crystals and penicillin, but the quantity of any salt of penicillin K therein is not more than 30 percent; procaine penicillin G is procaine penicillin which contains not less than 85 percent by weight of the procaine salt of penicillin G. Each such drug is so purified and dried that:

(1) Its potency is not less than 900 units per milligram;

(2) It is sterile;

(3) It is nonpyrogenic;

(4) It is nontoxic;

(5) Its moisture content is not more than 4.2 percent; and

(6) Its pH in saturated aqueous solution is not less than 5 and not more than 7.5.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of procaine penicillin shall bear on its outside wrapper or container and the immediate container as hereinafter indicated, the following:

(1) The batch mark;

(2) The weight of the drug and the number of units in the immediate containers;

(3) The statement "Expiration date ------------," the blank being filled in with the date which is 36 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 48 months after the month during which the batch was certified, if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate

container is packaged in an individual wrapper or container;

(4) The statement "For manufacturing use only";

(5) The statement "Caution: Federal law prohibits dispensing without prescription."

(d) *Request for certification, check tests and assays; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of procaine penicillin shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the weight of the drug and the number of units in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, sterility, toxicity, pyrogens, moisture, pH, crystallinity, penicillin K content (unless it is procaine penicillin G), and the penicillin G content if it is procaine penicillin G.

(2) Such person shall submit with his request an accurately representative sample of the batch, consisting of the following:

(i) For all tests except sterility; 10 packages.

(ii) For sterility testing; 10 packages.

Each such package shall contain approximately 300 milligrams taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(3) In connection with contemplated requests for certification of batches of another drug in the manufacture of which procaine penicillin is to be used, the manufacturer of a batch which is to be so used may request the Commissioner to make check tests and assays on a sample of such batch taken as prescribed by subparagraph (2) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to each manufacturer results of such check tests and assays as are so requested.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (2) (i) and (3) of this section; and

(2) If the Commissioner considers that investigations other than the examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.45 *Procaine penicillin in oil*—(a) *Standards of identity, strength, quality and purity.* Procaine penicillin in oil is a suspension of procaine penicillin in refined peanut oil or sesame oil, with or without the addition of one or more suitable and harmless dispersing agents and with or without the addition of a hardening agent. If it is intended solely for veterinary use and is conspicuously so labeled, it may contain nitrofurazone or adrenocorticotropic hormone (ACTH). Its potency is 300,000 units per milliliter, except if it is packaged and labeled solely for veterinary use, its potency is not less than 10,000 units per milliliter. Its moisture content is not more than 1.4 percent. It is sterile, unless it is packaged and labeled solely for udder instillations of cattle or subcutaneous injection in fowl. The procaine penicillin used conforms to the requirements of § 146a.44 (a), except if the batch of procaine penicillin in oil is packaged and labeled solely for udder instillation of cattle or subcutaneous injection in fowl, the penicillin used is exempt from the requirements of subparagraphs (2) and (3) of that section. The sesame oil and peanut oil used conform to the standards prescribed therefor by the U. S. P. The hardening agent is a refined hydrogenated and deodorized peanut oil free from rancidity; it has an iodine value of not more than 10; its free fatty acid content as oleic acid is not more than $\frac{1}{10}$ of 1 percent, and its melting point is 64° C., ±2° C.

(b) *Packaging.* The immediate container of procaine penicillin in oil shall be of colorless transparent glass (unless it is packaged to contain a single dose), so closed as to be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, and shall be so sealed that its contents cannot be used without destroying such seal, except if it is labeled solely for udder instillations of cattle or subcutaneous injection in fowl it may be packaged in plastic or collapsible tubes which shall be well-closed containers as defined by the U. S. P. The immediate container shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limitation therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good marketing, storage, and distribution practice shall be disregarded. The quantity of procaine penicillin in oil in each such container shall be not less than 1 milliliter and not more than 20 milliliters, unless it is packaged for repacking or is packaged and labeled solely for veterinary use. Unless it is packaged for repacking, each such container shall be filled with a volume of procaine penicillin in oil in excess of that designated, which excess shall be sufficient to permit the withdrawal and the administration of the volume indicated, whether administered in single or multiple doses.

(c) *Labeling.* Each package of procaine penicillin in oil shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container of the package:

(i) The batch mark;

(ii) The number of units per milliliter of the batch;

(iii) The statement "Expiration date ________________," the blank being filled in, if it is packaged in plastic containers, with the date which is 12 months, or if its container is not plastic, with the date which is 36 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 18 or 24 months, if the container is plastic, or 48 or 60 months if the container is not plastic, after the month during which the batch was certified, if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) Unless it is packaged and labeled solely for udder instillations of cattle or subcutaneous injection in fowl, the statement "For intramuscular use only" and, if it does not contain a hardening agent, "Shake well"; and

(v) The name of each oil used in making the batch and, if aluminum monostearate is used as the dispersing agent or if nitrofurazone or adrenocorticotropic hormone is used, the quantity used.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is intended solely for veterinary use and contains adrenocorticotropic hormone, the statement "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian."

(iii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled:

(i) If it contains adrenocorticotropic hormone, adequate directions and warnings for its use by veterinarians licensed by law to administer such drug.

(ii) If it does not contain adrenocorticotropic hormone, adequate directions and warnings for the veterinary use of such drug by the laity, including a statement, if it is intended for subcutaneous injection in fowl, that it should be injected in the neck immediately behind the head.

Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of procaine penicillin in oil shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the procaine penicillin used in making such batch was completed, the number of units in each of such packages, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that each ingredient used in making such batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility (unless it is intended solely for udder instillations of cattle or subcutaneous injection in fowl), and moisture.

(ii) The procaine penicillin used in making the batch; potency, toxicity, moisture, pH, crystallinity, penicillin K content (unless it is crystalline penicillin G), procaine penicillin G content if it is procaine penicillin G, and, unless the batch of procaine penicillin in oil is intended solely for udder instillations of cattle or subcutaneous injection in fowl, sterility or pyrogens.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility; one package for each 500 packages in the batch, but in no case less than 3 packages or more than 12 packages, unless it is intended solely for udder instillations of cattle or subcutaneous injections in fowl, in which case such sample shall consist of 1 package for each 5,000 packages in the batch, but in no case less than 5 packages or more than 12 packages.

(*b*) For sterility testing; 10 packages.

Such samples shall be collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The procaine penicillin used in making the batch:

(*a*) For all tests except sterility; 10 packages, each containing approximately equal portions of 300 milligrams.

(*b*) For sterility testing; 10 packages, each containing approximately equal portions of 300 milligrams.

Such samples shall be packaged in accordance with the requirements of § 146a.44 (b).

(iii) In case of an initial request for certification, the peanut oil or sesame oil and each dispersing and hardening agent or other ingredient used in making the batch; one package of each containing, respectively, approximately 250 grams and 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fees for the services rendered with respect to each batch of procaine penicillin in oil under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i) (*a*), (ii) (*a*), and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.46 *Crystalline penicillin for inhalation therapy*—(a) *Standards of identity, strength, quality, and purity.* Crystalline penicillin for inhalation therapy is crystalline sodium penicillin, potassium penicillin, or procaine penicillin, with or without one or more suitable and harmless diluents. Its moisture content is not more than 1.5 percent if it is crystalline sodium or potassium penicillin, and not more than 4.2 percent if it is procaine penicillin. The crystalline penicillin used conforms to the requirements of § 146a.24 (a) except subparagraphs (2) and (4) of that paragraph. The procaine penicillin used conforms to the requirements of § 146a.44 (a), except subparagraphs (2) and (3) of that paragraph. Each diluent used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* The immediate container of crystalline penicillin for inhalation therapy shall be a tight container as defined by the U. S. P.; its closure shall be one through which a hypodermic needle cannot be introduced; and the container shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each such container shall contain not less than 50,000 units and each may be packaged in combination with a container of the solvent, distilled water U. S. P., physiological salt solution U. S. P., physiological salt solution with the preservative chlorobutanol, or a solution of propylene glycol in distilled water.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in the immediate container;

(iii) The statement "Expiration date ----------------," the blank being filled in, if crystalline sodium penicillin or potassium penicillin is used, without a diluent, with the date which is 36 months, or if procaine penicillin is used, without a diluent, with the date which is 24 months, or if a diluent is used, with the date which is 18 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) If it is packaged in combination with a container of a solvent, the statement "Warning—Not for injection."

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription."

(ii) If it is packaged for dispensing, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of crystalline penicillin for inhalation therapy shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each immediate container, the quantity of each diluent used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each diluent used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following,

made by him on an accurately representative sample of:

(i) The batch; potency and moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, penicillin K content (unless it is crystalline penicillin G), crystallinity if it is crystalline penicillin, heat stability if it is crystalline sodium or potassium penicillin, the penicillin G content if it is crystalline sodium or potassium penicillin G, and the procaine penicillin G content if it is procaine penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers or more than 12 immediate containers, collected by taking single immediate containers, before or after labeling at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The penicillin used in making the batch; 10 packages, each containing approximately equal portions of not less than 60 milligrams if it is not procaine penicillin, and not less than 300 milligrams if it is procaine penicillin, packaged in accordance with the requirements of § 146a.24 (b) or § 146a.44 (b).

(iii) In case of an initial request for certification, each diluent used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (3) (i), (ii), and (iii) of this section.

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.47 *Procaine penicillin for aqueous injection*—(a) *Standards of identity, strength, quality, and purity.* Procaine penicillin for aqueous injection is a dry mixture of procaine penicillin and one or more suitable and harmless suspending or dispersing agents, with or without one or more suitable and harmless preservatives and buffer substances, or it is an aqueous suspension of procaine penicillin and one or more suitable and harmless suspending or dispersing agents, buffer substances, and preservatives, except that preservatives are not required if the immediate container is packaged to contain a single dose and is conspicuously so labeled. If it is an aqueous suspension of the drug it may contain procaine hydrochloride in a concentration not exceeding 2 percent and one or more suitable and harmless stabilizing agents. It is so purified that:

(1) If it is an aqueous suspension of the drug, each container or each milliliter shall contain not less than 300,000 units;

(2) It is sterile;

(3) If it is the dry mixture of the drug, its moisture content is not more than 4.2 percent;

(4) It is nonpyrogenic;

(5) It is nontoxic; and

(6) Its pH in saturated aqueous solution is not less than 5.0 and not more than 7.5.

The procaine penicillin used conforms to the requirements of § 146a.44 (a). Each other substance, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing, it shall be in immediate containers of colorless, transparent glass, closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness, unless it is the aqueous suspension of the drug and it is packaged to contain a single dose. If it is the dry mixture of the drug, each such container shall contain 300,000 units, 600,000 units, 900,000 units, 1,200,000 units, 1,500,000 units, or 3,000,000 units, unless it is intended solely for veterinary use and it is conspicuously so labeled. Each such container may be packaged in combination with a container of a suitable aqueous diluent. If it is the aqueous suspension of the drug, each such container shall contain not less than 1 milliliter (unless it is packaged to contain a single dose) and not more than 12 milliliters (unless it is intended solely for veterinary use and is conspicuously so labeled), and each shall be filled with a volume in excess of that designated, which excess shall be sufficient to permit the withdrawal and the administration of the volume indicated, whether administered in either single or multiple doses.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in the immediate container;

(iii) The statement "Expiration date ------," the blank being filled in, if it is a dry mixture of the drug, with the date which is 36 months, or if it is the aqueous suspension of the drug, with the date which is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 48 months, if it is the dry mixture of the drug, and 18 months or 24 months, if it is the aqueous suspension of the drug, after the month during which the batch was certified, if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) The statement "For intramuscular use only"; and

(v) If the drug contains preservatives or added procaine hydrochloride, the name and quantity of each such added ingredient.

(2) On the immediate container, if it is a dry mixture of the drug, the conditions under which suspensions made from such drug should be stored, and the statement "Sterile suspension may be kept at room temperature for 1 week, or in a refrigerator for 3 weeks, without significant loss of potency," unless this information is contained in a circular or other labeling within or attached to the package.

(3) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(iii) If it is the aqueous suspension of the drug, the statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)," unless the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section after having been stored at room temperature.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of procaine penicillin for aqueous injection shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the procaine penicillin used in making such batch was completed, the number of units in each of such packages, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section. If such batch, or any part thereof, is to be packaged with a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (5) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, moisture, pyrogens, toxicity, pH.

(ii) The procaine penicillin used in making the batch; potency, crystallinity, penicillin K content (unless it is procaine penicillin G), and the penicillin G content if it is procaine penicillin G.

(3) Except as otherwise provided by subparagraph (5) of this paragraph, if such batch is packaged for dispensing, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility; one immediate container for each 5,000 immediate containers in such batch, but in no case less than 10 or more than 17 immediate containers.

(*b*) For sterility testing; 10 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The procaine penicillin used in making the batch; 3 packages containing approximately equal portions of not less than 500 milligrams each, packaged in accordance with the requirements of § 146a.44 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(iv) In case of an initial request for the certification of a batch of procaine penicillin for aqueous injection which is to be packaged in combination with an aqueous diluent which is not recognized by the U. S. P., or when any change is made in the composition of such diluent, five packages of the diluent included in the combination.

(4) If such batch is packaged for repacking, such person shall submit with his request a sample consisting of the following:

(i) For all tests except sterility; 10 packages.

(ii) For sterility testing; 10 packages.

Each such package shall contain not less than approximately 300 milligrams taken from different parts of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(5) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (3) (i) (*a*), (ii), (iii), (iv), and (4) (i) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.48 *Ephedrine penicillin (penicillin ephedrine salt), ephedrine penicillin G (penicillin G ephedrine salt)*—(a) *Standards of identity, strength, quality, and purity.* Ephedrine penicillin is the crystalline ephedrine salt of a kind of penicillin, or a mixture of two or more such salts prepared from ephedrine U. S. P. and penicillin, but the quantity of any salt of penicillin K therein is not more than 30 percent; ephedrine penicillin G is ephedrine penicillin which contains not less than 85 percent by weight of the ephedrine salt of penicillin G. Each such drug is so purified and dried that:

(1) Its potency is not less than 1,000 units per milligram;

(2) It is sterile;

(3) It is nontoxic;

(4) It is nonpyrogenic;

(5) Its moisture content is not more than 1.5 percent;

(6) Its pH in aqueous solution of 5,000 to 10,000 units per milliliter is not less than 5 and not more than 7.5.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of ephedrine penicillin shall bear on its outside wrapper or container and the immediate container as hereinafter indicated, the following:

(1) The batch mark;

(2) The weight of the drug and the number of units in the immediate container;

(3) The statement "Expiration date ---------------", the blank being filled in with the date which is 12 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted form the immediate container if such immediate container is packaged in an individual wrapper or container;

(4) The statement "For manufacturing use only;"

(5) The statement "Caution: Federal law prohibits dispensing without prescription."

(d) *Requests for certification, check tests and assays; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of ephedrine penicillin shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the weight of the drug and the number of units in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, sterility, toxicity, pyrogens, moisture, pH, crystallinity, penicillin K content (unless it is ephedrine penicillin G), and the penicillin G content if it is ephedrine penicillin G.

(2) Such person shall submit with his request an accurately representative sample of the batch, consisting of the following:

(i) For all tests except sterility; 10 packages.

(ii) For sterility testing; 10 packages.

Each such package shall contain approximately 300 milligrams taken from a different part of such bath, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(3) In connection with the contemplated requests for certification of batches of another drug in the manufac-

ture of which ephedrine penicillin is to be used, the manufacturer of a batch which is to be so used may request the Commissioner to make check tests and assays on a sample of such batch taken as prescribed by subparagraph (2) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to each manufacturer results of such check tests and assays as are so requested.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (2) (i) and (3) of this section; and

(2) If the Commissioner considers that investigations other than the examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed under subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.49 *Ephedrine penicillin tablets*—(a) *Standards of identity strength, quality, and purity.* Ephedrine penicillin tablets are tablets composed of ephedrine penicillin and one or more buffer substances, with or without one or more suitable and harmless diluents, binders, and lubricants. The potency of each tablet is not less than 30,000 units. Its moisture content is not more than 1.5 percent. When a tablet is dissolved as directed the potency of such solution is not less than 4,000 units per milliliter after it has been kept for one day at a temperature of 15° C. (59° F). Such solution is isotonic, and has a pH of 6.0, ±0.2. The ephedrine penicillin used conforms to the requirements of § 146a.48 (a) for ephedrine penicillin except subparagraphs (2) and (4) of § 146a.48 (a). Each buffer substance and preservative used, if their names are recognized in the U. S. P. or N. F., conform to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each tablet is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the tablets by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of tablets ephedrine penicillin shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in each tablet of the batch;

(iii) The statement "Expiration date --------," the blank being filled in with the date which is 24 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) A statement giving the method of dissolving the tablets, and a statement that distilled water U. S. P. should be used;

(v) The potency per milliliter after the tablet has been dissolved therein;

(vi) The statement "Warning—Not for injection or oral use"; and

(vii) The conditions under which the solution should be stored including a reference to its instability when stored under other conditions, and a statement "Prepare a fresh solution each 24 hours."

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of ephedrine penicillin tablets shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the ephedrine penicillin used in making such batch was completed, the number of units in each tablet, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising the batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per tablet and average moisture.

(ii) The ephedrine penicillin used in making the batch; potency, toxicity, moisture, pH, penicillin K content (unless it is ephedrine penicillin G), crystallinity, and the penicillin G content if it is ephedrine penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one tablet for each 5,000 tablets in the batch, but in no case less than 20 tablets or more than 100 tablets, collected by taking single tablets at such intervals throughout the entire time of tableting that the quantities tableted during the intervals are approximately equal.

(ii) The ephedrine penicillin used in making the batch; six packages, each containing approximately equal portions of not less than 300 milligrams, packaged in accordance with the requirements of § 146a.48 (b).

(iii) In case of an initial request for certification, each buffer substance, diluent, binder, and lubricant used in making the batch; one package of each, each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for services rendered with respect to each batch of ephedrine penicillin tablets under the regulations in this part shall be:

(1) $1.00 for each tablet in the sample submitted in accordance with paragraph (d) (3) (i) of this section, $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such tablets and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations. The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.50 *Procaine penicillin and buffered crystalline penicillin for aqueous* *injection.* Procaine penicillin and buffered crystalline penicillin for aqueous injection conforms to all requirements prescribed by § 146a.47 for the dry mixture of procaine penicillin for aqueous injection, and is subject to all procedures prescribed by § 146a.47 for the dry mixture of procaine penicillin for aqueous injection, except that:

(a) Each immediate container shall contain not less than 50,000 units of buffered crystalline penicillin for each 300,000 units of procaine penicillin. The buffered crystalline penicillin conforms to the requirements prescribed by § 146a.37.

(b) If it is packaged as a single dose and its immediate container has two compartments separated by a tight rubber seal, one compartment shall contain an aqueous suspension of procaine penicillin which conforms to all requirements and procedures prescribed by § 146a.47 and one compartment shall contain the dry buffered crystalline penicillin.

(c) In lieu of the directions prescribed for procaine penicillin for aqueous injection by § 146a.47 (c) (1) (ii), each package shall bear on the outside wrapper or container and the immediate container the number of units of procaine penicillin and the number of units of buffered crystalline penicillin in the immediate container; the circular or other labeling within or attached to the package, if it is packaged for dispensing, shall bear, in lieu of the statement prescribed by § 146a.47 (c) (2), the statement "Sterile suspension may be kept in refrigerator for ------ week(s) without significant loss of potency," the blank being filled in with the figure "1," or if the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug as prepared by him does not lose significant potency after having been stored in a refrigerator for 4 weeks, the blank may be filled in with the figure "4," unless it is packaged to conform with paragraph (b) of this section.

(d) In addition to complying with the requirements of § 146a.47 (d), a person who requests certification of a batch of procaine penicillin and buffered crystalline penicillin for aqueous injection shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the buffered crystalline penicillin used in making the batch for potency, crystallinity, heat stability, penicillin K content (unless it is buffered crystalline penicillin G) and the penicillin G content if it is buffered crystalline penicillin G, the number of units of procaine penicillin and the number of units of buffered crystalline penicillin in each immediate container of the batch. He shall also submit in connection with his request a sample consisting of three packages containing approximately equal portions of not less than 250 milligrams each of the buffered crystalline penicillin used in making the batch. If such batch is packaged for repacking, each portion in the sample required by § 146a.47 (d) (4) shall consist of approximately 400 milligrams in lieu of 300 milligrams.

(e) The fee for the services rendered with respect to each immediate container in the sample of buffered crystalline penicillin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146a.51 *Buffered penicillin powder, penicillin powder with buffered aqueous diluent*—(a) *Standards of identity, strength, quality, and purity.* Buffered penicillin powder is a mixture of crystalline penicillin or procaine penicillin and suitable buffer substances, with or without probenecid, sodium salicylate and a suitable antihistaminic agent, with or without one or more suitable sulfonamides, and with or without the addition of one or more suitable and harmless diluents, colorings, and flavorings. Penicillin powder with buffered aqueous diluent is a packaged combination of one immediate container of crystalline penicillin or procaine penicillin, with or without suitable and harmless diluents, and one immediate container of an aqueous diluent containing suitable buffer substances and suitable and harmless preservatives, colorings, and flavorings. Its moisture content is not more than 1.0 percent, except if it contains procaine penicillin its moisture content is not more than 2.0 percent. The crystalline penicillin used conforms to the requirements of § 146a.24 (a) for crystalline penicillin, except subparagraphs (2) and (4) of that paragraph. The procaine penicillin used conforms to the requirements of § 146a.44 (a), except subparagraphs (2) and (3) of that paragraph. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate container of buffered penicillin powder shall be a tight container as defined by the U. S. P. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limits therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each immediate container may be packaged in combination with a container of a suitable and harmless aqueous vehicle, with or without probenecid, and with or without one or more suitable sulfonamides.

(c) *Labeling.* Each package of buffered penicillin powder or penicillin powder shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in the immediate container;

(iii) If the batch contains, in addition to penicillin, one or more of the other active ingredients specified in paragraph (a) of this section, the name and quantity of each such other ingredient in the immediate container;

(iv) If it is a packaged combination of one immediate container of buffered penicillin powder or penicillin powder and one immediate container of a vehicle, a statement giving the method of dissolving the penicillin;

(v) The name of each buffer substance used in making the batch;

(vi) The statement "Expiration date --------," the blank being filled in with the date which is 24 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 36 months after the month during which the batch was certified if it is crystalline penicillin with no other ingredients, or if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(vii) The statement "Warning—Not for injection."

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the label and labeling if it contains, in addition to penicillin, one or more of the other active ingredients specified in paragraph (a) of this section, after the name "buffered penicillin powder," wherever it appears, the words "with ------ (the blank being filled in with the common or usual name of each such other ingredient)," in juxtaposition with such name.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of buffered penicillin powder shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the number of units in each immediate container, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; if buffered penicillin powder or penicillin powder with diluents: potency and moisture; if penicillin powder with no other ingredients: potency toxicity, moisture, pH, penicillin K content (unless it is crystalline penicillin G), crystallinity, heat stability if it is crystalline sodium or potassium penicillin, the penicillin G content if it is crystalline sodium or potassium penicillin G, and the procaine penicillin G content if it is procaine penicillin G.

(ii) If buffered penicillin powder or penicillin powder with diluents, the penicillin used in making the batch; potency, toxicity, moisture, pH, penicillin K content (unless it is crystalline penicillin G), crystallinity, heat stability if it is crystalline sodium or potassium penicillin, the penicillin G content if it is crystalline sodium or potassium penicillin G, and the procaine penicillin G content if it is procaine penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) If it contains only penicillin and the penicillin used has been previously submitted, or it contains penicillin and other ingredients; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers or more than 12 immediate containers.

(*b*) If it contains only penicillin and the penicillin has not been previously submitted; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 10 immediate containers or more than 17 immediate containers.

Such sample shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) If buffered pencillin powder or penicillin powder with diluents, the penicillin used in making the batch; 10 packages, each containing approximately equal portions of not less than 60 milligrams if it is not procaine penicillin, and not less than 500 milligrams if it is procaine penicillin, packaged in accordance with the requirements of § 146a.24 (b) or § 146a.44 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(iv) In case of an initial request for the certification of a batch of buffered penicillin powder which is to be packaged in combination with an aqueous vehicle, or when any change is made in the composition of such aqueous vehicle; 5 packages of the vehicle included in the combination.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of buffered penicillin powder under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (3) (i), (ii), (iii), and (iv) of this section.

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

(f) *Exemption of buffered penicillin powder and penicillin powder with buffered aqueous diluent for veterinary use from certification.* Buffered penicillin powder and penicillin powder with buffered aqueous diluent that conform to the requirements of paragraphs (a) (except that they may contain one or more essential vitamin and mineral substances for nutritive purposes), (b), and (c) of this section shall be exempt from the requirements of sections 502 (l) and 507 of the act, if they comply with all the following conditions:

(1) They are intended solely for veterinary use and are conspicuously so labeled.

(2) If they contain added vitamins or minerals, the labels bear the name and quantity of each such substance and a statement that such substances are present only for furnishing additional vitamins and minerals while animals are eating less feed.

(3) The labels bear an expiration date that is not more than 36 months after the month during which the batch was last assayed and released by the manufacturer.

(4) The labels bear a statement that solutions prepared with the drugs are stable for not more than 24 hours.

(5) The circular or other labeling within or attached to the package bears information that only the antibiotics are intended for the prevention or treatment of the following conditions, and further, bears directions and warnings adequate for such use:

(i) Chronic respiratory disease (airsac infection) in chickens.

(ii) Blue comb (mud fever, nonspecific infectious enteritis) in poultry.

(iii) Infectious sinusitis in poultry.

§ 146a.52 *Procaine penicillin and crystalline penicillin in oil.* (a) Procaine penicillin and crystalline penicillin in oil conforms to all requirements prescribed by § 146a.45 for procaine penicillin in oil, and is subject to all procedures prescribed by § 146a.45 for procaine penicillin in oil, except that:

(1) It contains not less than 50,000 units of crystalline penicillin for each 300,000 units of procaine penicillin, except if it is packaged and labeled solely for veterinary use, it contains not less than 3,000 units of crystalline penicillin for each 10,000 units of procaine penicillin. The crystalline penicillin used conforms to the requirements prescribed therefor by § 146a.24 (a), except if the batch of procaine penicillin and crystalline penicillin in oil is intended solely for udder instillations of cattle, the crystalline penicillin used is exempt from the requirements of subparagraphs (2) and (4) of that paragraph.

(2) In lieu of the directions prescribed for procaine penicillin in oil by § 146a.45 (c) (1) (ii), each package shall bear on the outside wrapper or container and the immediate container the number of units of procaine penicillin and the number of units of crystalline penicillin in each milliliter of the batch.

(3) In addition to complying with the requirements of § 146a.45 (d), a person who requests certification of a batch of procaine penicillin and crystalline penicillin in oil shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the crystalline penicillin G used in making the batch for potency, toxicity, moisture, pH, penicillin K content (unless it is crystalline penicillin G), crystallinity, heat stability, the penicillin G content if it is crystalline penicillin G, and, unless the batch of procaine penicillin and crystalline penicillin in oil is intended solely for udder instillations of cattle, sterility and pyrogens; the number of units of procaine penicillin and the number of units of crystalline penicillin in each milliliter of the batch. In addition to the 10 immediate containers required by § 146a.45 (d) (3) (i) (*b*), he shall also submit in connection with his request a sample consisting of not less than 4 packages, unless it is intended solely for udder instillations of cattle in which case such sample shall consist of not less than 6 packages, of the batch of procaine penicillin and crystalline penicillin in oil and a sample of the crystalline penicillin used in making the batch, consisting of 10 packages, each containing approximately equal portions of not less than 60 milligrams, and 10 packages, each containing approximately equal portions of not less than 300 milligrams.

(b) The fee for the services rendered with respect to each 60-milligram package of crystalline penicillin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146a.54 *Penicillin-streptomycin ointment (penicillin-streptomycin mineral oil suspension); penicillin-dihydrostreptomycin ointment (penicillin-dihydrostreptomycin mineral oil suspension.)* (a) Penicillin-streptomycin ointment and penicillin-dihydrostreptomycin ointment conform to all requirements prescribed by § 146a.26 for penicillin ointment, except paragraph (c) (2) (i) of that section, and are subject to all procedures prescribed by § 146a.26 for penicillin ointment, except that:

(1) It contains not less than 2,000 units of penicillin per gram.

(2) It contains not less than 10 milligrams of streptomycin or dihydrostreptomycin per gram, unless it is intended solely for veterinary use and is conspicuously so labeled. The streptomycin used conforms to the standards prescribed by § 146b.101 (a) of this chapter, except subparagraphs (2), (4), and (5) of that paragraph. The dihydrostreptomycin used conforms to the standards prescribed by § 146b.103 of this chapter, except the standards for sterility, pyrogens, and histamine.

(3) If it is intended solely for veterinary use and is conspicuously so labeled, it may contain a suitable and harmless salt of cobalt, one or more sulfonamides, and one or more suitable and harmless preservatives; and if it is packaged and labeled solely for udder instillations of cattle it may contain papain.

(b) In lieu of the directions prescribed for penicillin ointment by § 146a.26 (c) (1) (ii), each package shall bear on the outside wrapper or container and the immediate container the number of units of penicillin per gram and the number of milligrams of streptomycin or dihydrostreptomycin per gram, and if it contains cobalt, preservatives, sulfonamides, or papain, the quantity of each.

(c) In addition to complying with the requirements of § 146a.26 (d), a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and date of the latest tests and assays of the streptomycin or dihydrostreptomycin used in making the batch for potency, toxicity, moisture, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin sulfate. He shall also submit in connection with his request a sample consisting of not less than six packages of such ointment and (unless it was previously submitted) a sample consisting of five packages containing approximately equal portions of not less than 0.5 gm. each of the streptomycin or dihydrostreptomycin used in making the batch, packaged in accordance with the requirements of § 146b.101 (b) of this chapter.

(d) The fee for the services rendered with respect to each immediate container in the sample of streptomycin or dihydrostreptomycin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146a.55 *Penicillin-streptomycin bougies; penicillin - dihydrostreptomycin bougies.* (a) Penicillin-streptomycin bougies and penicillin-dihydrostreptomycin bougies conform to all requirements prescribed by § 146a.40 for penicillin bougies, except paragraph (c) (1) (iv) of that section, and are subject to all procedures prescribed by § 146a.40 for penicillin bougies, except that:

(1) Each bougie contains not less than 25 milligrams of streptomycin or dihydrostreptomycin.

(2) In lieu of the directions prescribed for penicillin bougies by § 146a.40 (c) (1) (ii), each package shall bear on the outside wrapper or container and the immediate container the number of units of penicillin and the number of milligrams of streptomycin or dihydrostreptomycin in each bougie.

(3) In addition to complying with the requirements of § 146a.40 (d), a person who requests certification of a batch of penicillin-streptomycin bougies or penicillin-dihydrostreptomycin bougies shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the streptomycin or dihydrostreptomycin used in making the batch for potency, toxicity, moisture, pH, and its streptomycin content if it is dihydrostreptomycin; the number of units of penicillin and the number of milligrams of streptomycin or dihydrostreptomycin in each bougie of the batch. He shall also submit in connection with his request a sample consisting of not less than thirty bougies and (unless it was previously submitted) a sample consisting of five packages containing approximately equal portions of not less than 0.5 gram each of the streptomycin or dihydrostreptomycin used in making the batch, packaged in accordance with the requirements of § 146b.101 (b) of this chapter.

(b) The fee for the services rendered with respect to each immediate container in the sample of streptomycin or dihydrostreptomycin submitted in accordance with the requirements prescribed by this section shall be $4.00.

§ 146a.56 *Penicillin-bacitracin ointment.* (a) Penicillin-bacitracin ointment conforms to all requirements prescribed by § 146a.26 for penicillin ointment and is subject to all procedures prescribed by § 146a.26 for penicillin ointment, except that:

(1) It contains not less than 2,000 units of penicillin per gram;

(2) It contains not less than 500 units of bacitracin per gram;

(3) In lieu of the directions prescribed for penicillin ointment by § 146a.26 (c) (1) (ii) each package shall bear on the outside wrapper or container and the immediate container the number of units of penicillin per gram and the number of units of bacitracin per gram;

(4) In addition to complying with the requirements of § 146a.26 (d) a person who requests certification of a batch of penicillin-bacitracin ointment shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and date of the latest tests and assays of the bacitracin used in making the batch for potency, toxicity, moisture, and pH. He shall also submit in connection with his request a sample consisting of not less than six packages of penicillin-bacitracin ointment and (unless it was previously submitted) a sample consisting of six packages containing approximately equal portions of not less than 0.5 gram each of the bacitracin used in making the batch, packaged in accordance with the requirements of § 146e.401 (b) of this chapter.

(b) The fee for the services rendered with respect to each immediate container in the sample of bacitracin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146a.57 *Procaine penicillin and streptomycin in oil; procaine penicillin and dihydrostreptomycin in oil.* (a) Procaine penicillin and streptomycin in oil and procaine penicillin and dihydrostreptomycin in oil conform to all requirements and to all procedures prescribed in § 146a.45 for procaine penicillin in oil for udder instillations of cattle or subcutaneous injection in fowl, except that:

(1) It contains not less than 2.0 milligrams of streptomycin or dihydrostreptomycin per milliliter. The streptomycin used conforms to the standards prescribed by § 146b.101 (a) of this chapter, except subparagraphs (2), (4), and (5) of that paragraph. The dihydrostreptomycin used conforms to the standards prescribed by § 146b.103 of this chapter, except the standards for sterility, pyrogens, and histamine.

(2) It may contain a suitable and harmless salt of cobalt and/or one or more suitable sulfonamides and papain, if it is intended solely for udder instillations of cattle, each of which, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(3) In lieu of the labeling prescribed for procaine penicillin in oil by § 146a.45 (c) (1) (ii) and (iv), each package shall bear on the outside wrapper or container and the immediate container the number of units of penicillin and the number of milligrams of streptomycin or dihydrostreptomycin per milliliter or prescribed dose; if it contains one or more of the active ingredients specified in subparagraph (2) of this paragraph, the name and quantity of each; the statement "For udder instillations of cattle only" or the statement "For subcutaneous injection in fowl only"; and if it is a multiple-dose container, the statement "Shake well." Each package shall also bear on its label and labeling, if it contains one or more of the other active ingredients specified in subparagraph (2) of this paragraph, after the name "Procaine penicillin and streptomycin in oil" or "Procaine penicillin and dihydrostreptomycin in oil," wherever it appears, the words "with ------------ (the blank being filled in with the common or usual name of each such other ingredient)," in juxtaposition with such name.

(4) In addition to complying with the requirements of § 146a.45 (d), a person who requests certification of a batch of

procaine penicillin and streptomycin in oil or procaine penicillin and dihydrostreptomycin in oil shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the streptomycin or dihydrostreptomycin used in making the batch for potency, toxicity, moisture, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin; the number of units of penicillin and the number of milligrams of streptomycin or dihydrostreptomycin in each milliliter of the batch or in each prescribed dose. He shall also submit in connection with his request a sample consisting of not less than six immediate containers of the batch and (unless it was previously submitted) a sample consisting of five packages containing approximately equal portions of not less than 0.5 gram each of the streptomycin or dihydrostreptomycin used in making the batch, packaged in accordance with the requirements of § 146b.101 (b) of this chapter.

(b) The fee for the services rendered with respect to each immediate container in the sample of streptomycin or dihydrostreptomycin submitted in accordance with the requirements prescribed by this section shall be $4.00.

§ 146a.58 *Penicillin and streptomycin; penicillin and dihydrostreptomycin*—(a) *Standards of identity, strength, quality, and purity.* Penicillin and streptomycin is procaine penicillin or crystalline sodium penicillin or potassium penicillin or *l*-ephenamine penicillin G or a mixture of procaine penicillin and crystalline sodium penicillin or potassium penicillin and streptomycin sulfate. Penicillin and dihydrostreptomycin is procaine penicillin or crystalline sodium penicillin or potassium penicillin or *l*-ephenamine penicillin G or a mixture of procaine penicillin and crystalline sodium penicillin or potassium penicillin and dihydrostreptomycin sulfate. Each such drug may contain suitable and harmless buffer substances, and suspending or dispersing agents. It is so purified and dried that:

(1) It is sterile;

(2) It is nontoxic;

(3) It is nonpyrogenic;

(4) Its moisture content is not more than 3.5 percent, except if it contains procaine penicillin its moisture content is not more than 4.2 percent; and

(5) When prepared for injection as directed in its labeling its pH is not less than 5.0 and not more than 7.5.

The procaine penicillin used conforms to the requirements prescribed by § 146a.44 (a). The crystalline penicillin used conforms to the requirements prescribed for crystalline penicillin by § 146a.24 (a). The *l*-ephenamine penicillin G used conforms to the requirements prescribed for *l*-ephenamine penicillin G by § 146a.64 (a). The streptomycin sulfate used conforms to the requirements prescribed by § 146b.101 (a) of this chapter. The dihydrostreptomycin sulfate used conforms to the requirements prescribed by § 146b.106 (a) of this chapter. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases, the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing, it shall be in immediate containers of colorless (unless it is intended solely for veterinary use), transparent glass, closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness. Unless it is intended solely for veterinary use and is conspicuously so labeled, each such container shall contain 300,000 units, 600,000 units, 900,000 units, 1,500,000 units or 3,000,000 units of procaine penicillin or crystalline sodium penicillin or potassium penicillin or *l*-ephenamine penicillin G and not less than 0.25 gram of streptomycin or dihydrostreptomycin for each 300,000 units of penicillin, except if it is a mixture of two salts of penicillin it shall contain not less than 100,000 units of crystalline sodium penicillin or potassium penicillin for each 300,000 units of procaine penicillin. Each such container may be packaged in combination with a container of a solvent, water for injection U. S. P., dextrose injection U. S. P., or physiological salt solution U. S. P.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units of each salt of penicillin in the immediate container;

(iii) The number of grams of streptomycin or dihydrostreptomycin in the immediate container;

(iv) The statement "Expiration date ____," the blank being filled in with the date which is 48 months after the month in which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(v) The statement "For intramuscular use only"; and

(vi) The statement "For manufacturing use," "For repacking," or "For manufacturing use or repacking," when packaged for repacking or for use as an ingredient in the manufacture of another drug, as the case may be.

(2) On the outside wrapper or container the statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing:

(i) If it is intended for use by man, adequate directions and warnings for its use by practitioners licensed by law to administer such drug.

(ii) If it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of penicillin and streptomycin or penicillin and dihydrostreptomycin shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the number of units of each salt of penicillin, and the number of grams of streptomycin or dihydrostreptomycin in each package, the batch marks, and (unless they were previously submitted) the dates on which the latest assays of the penicillin and streptomycin or dihydrostreptomycin used in making such batch were completed, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch and a statement that each such ingredient conforms to the requirements prescribed therefor by this section. If such batch, or any part thereof, is to be packaged with a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (5) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, toxicity, pyrogens, moisture, pH.

(ii) The procaine penicillin used in making the batch; potency, crystallinity, penicillin K content (unless it is procaine penicillin G), and the penicillin G content if it is procaine penicillin G.

(iii) The crystalline sodium or potassium penicillin used in making the batch; potency, crystallinity, heat stability, penicillin K content (unless it is crystalline penicillin G), and the penicillin G content if it is crystalline penicillin G.

(iv) The *l*-ephenamine penicillin G used in making the batch; potency, crystallinity, heat stability, penicillin G content, and specific rotation.

(v) The streptomycin or dihydrostreptomycin used in making the batch; potency, histamine content, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin.

(3) Except as otherwise provided by subparagraph (5) of this paragraph, if

such batch is packaged for dispensing, such person shall submit in connection with his request in the quantities hereinafter indicated accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility; one immediate container for each 5,000 immediate containers in such batch, but in no case less than 12 or more than 19 immediate containers.

(*b*) For sterility testing; 10 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The procaine penicillin used in making the batch; 3 packages containing approximately equal portions of not less than 0.5 gram each packaged in accordance with the requirements of § 146a.44 (b).

(iii) The crystalline penicillin used in making the batch, 3 packages containing approximately equal portions of not less than 250 milligrams each packaged in accordance with the requirements of § 146a.24 (b).

(iv) The *l*-ephenamine penicillin G used in making the batch; 3 packages containing approximately equal portions of not less than 0.5 gram each packaged in accordance with the requirements of § 146a.64 (b).

(v) The streptomycin or dihydrostreptomycin used in making the batch; 3 packages containing approximately equal portions of not less than 0.5 gram each packaged in accordance with the requirements of § 146b.101 (b) of this chapter.

(vi) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(4) If such batch is packaged for repacking, such person shall submit with his request a sample consisting of the following:

(i) For all tests except sterility; 12 approximately equal portions of at least 2 grams.

(ii) For sterility testing; 10 approximately equal portions of at least 0.5 gram.

Each such portion shall be taken from a different part of such batch, and each shall be packaged in a separate container and in accordance with the requirements of paragraph (b) of this section.

(5) No result referred to in subparagraph (2) (ii), (iii), and (iv) of this paragraph, and no sample referred to in subparagraph (3) (ii), (iii), and (iv) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (3) (i) (*a*), (ii), (iii), (iv), (v), (vi) and (4) (i) of this section; and

(2) If the Commissioner considers that investigations other than examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.59 *Penicillin tooth powder (tooth powder with penicillin)*—(a) *Standards of identity, strength, quality, and purity.* Penicillin tooth powder is a mixture of crystalline penicillin and one or more suitable cleansing and polishing substances, with or without suitable and harmless diluents, colorings, and flavorings. Its potency is 500 units per gram. Its moisture content is not more than 2.0 percent. The crystalline penicillin used conforms to the requirements of § 146a.24 (a) for crystalline penicillin, except the limitation on penicillin K content and except subparagraphs (2) and (4) of that paragraph. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each such container shall contain not more than 3 ounces.

(c) *Labeling.* Each package of penicillin tooth powder shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units per gram of the batch;

(iii) The statement "Expiration date ----------------," the blank being filled in with the date which is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 18 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription."

(ii) A reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of penicillin tooth powder shall submit with his request a statement showing the batch mark, the number of of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the penicillin used in making such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency and moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, crystallinity, heat stability, and the penicillin G content if it is crystalline sodium or potassium penicillin G.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers or more than 12 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The penicillin used in making the batch; 10 packages, each containing approximately equal portions of not less than 60 milligrams, packaged in accordance with the requirements of § 146a.24 (b).

(iii) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin tooth powder under the regulations in this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) (3) (i), (ii), and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.60 *Penicillin-bacitracin troches.* (a) Penicillin-bacitracin troches conform to all the requirements prescribed by § 146a.30 for penicillin troches, and are subject to all procedures prescribed by § 146a.30 for penicillin troches, except paragraph (f) of that section, and except that:

(1) Each troche shall contain not less than 50 units of bacitracin. The bacitracin used conforms to the standards prescribed by § 146e.401 (a) of this chapter, except subparagraphs (1), (2), and (4) of that paragraph, but its potency is not less than 30 units per milligram.

(2) In lieu of the labeling prescribed for penicillin troches by § 146a.30 (c) (1) (ii), each package shall bear on the outside wrapper or container and the immediate container the number of units of penicillin and the number of units of bacitracin in each troche of the batch.

(3) In addition to complying with the requirements of § 146a.30 (d), a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the bacitracin used in making the batch for potency, toxicity, moisture, and pH. He shall also submit in connection with his request a sample consisting of not less than 30 troches of such batch and (unless it was previously submitted) a sample consisting of 6 packages, each containing approximately equal portions of not less than 500 milligrams of the bacitracin used in making the batch, packaged in accordance with the requirements of § 146e.401 (b) of this chapter.

(b) The fee for the services rendered with respect to each immediate container in the sample of bacitracin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146a.63 *Crystalline penicillin and bacitracin*—(a) *Standards of identity, strength, quality, and purity.* Crystalline penicillin and bacitracin is composed of crystalline sodium penicillin or potassium penicillin and bacitracin with or without suitable and harmless buffer substances and dispersing agents. It is so purified and dried that:

(1) It is sterile;

(2) It is nontoxic;

(3) It is nonpyrogenic;

(4) Its moisture content is not more than 5.0 percent;

(5) The pH of an aqueous solution prepared as directed in its labeling is not less than 5.0 and not more than 7.5.

The crystalline penicillin used conforms to the standard prescribed by § 146a.24 (a). The bacitracin used conforms to the requirements prescribed by § 146e.401 (a) of this chapter. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practices shall be disregarded. In case it is packaged for dispensing, it shall be in immediate containers of colorless transparent glass, closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness; each such container shall contain 1,500,000 units of crystalline penicillin and 60,000 units of bacitracin and each may be packaged in combination with a container of the solvent, water for injection U. S. P., physiological salt solution U. S. P., or with an aqueous solution of a suitable local anesthetic.

(c) *Labeling.* Each package shall bear on it label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units of crystalline penicillin in the immediate container;

(iii) The number of units of bacitracin in the immediate container;

(iv) The statement "For intramuscular use only";

(v) The statement "Expiration date ______________," the blank being filled in with the date which is 18 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(vi) The statement "For manufacturing use," "For repacking," or "For manufacturing use or repacking," when packaged for repacking or for use as an ingredient in the manufacture of another drug, as the case may be.

(2) On the outside wrapper or container the statement "Caution: Federal law prohibits dispensing without prescription."

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing:

(i) Adequate directions and warnings for its use by practitioners licensed by law to administer such drug.

(ii) The conditions under which such solutions should be stored, including a reference to their instability when stored under other conditions, and the statement "Sterile solution may be kept in refrigerator for 3 days without significant loss of potency."

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of crystalline penicillin and bacitracin shall submit with his request a statement showing the batch mark, the number of packages in such batch, the number of units of penicillin and the number of units of bacitracin in each package, the batch marks, and (unless they were previously submitted) the dates on which the latest assays of the penicillin and bacitracin used in making such batch were completed, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch and a statement that each such ingredient conforms to the requirements prescribed therefor by this section. If such batch,, or any part thereof, is to be packaged with a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (5) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following made by him on an accurately representative sample of:

(i) The batch; potency, sterility, toxicity, pyrogens, moisture, pH.

(ii) The crystalline penicillin used in making the batch; potency, crystallinity, heat stability, penicillin K content (unless it is crystalline penicillin G), and the penicillin G content if it is crystalline penicillin G.

(iii) The bacitracin used in making the batch; potency and toxicity.

(3) Except as otherwise provided by subparagraph (5) of this paragraph, if such batch is packaged for dispensing, such person shall submit in connection with his request in the quantities hereinafter indicated accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility; one immediate container for each 5,000 immediate containers in such batch, but in no case less than 10 or more than 17 immediate containers.

(*b*) For sterility testing; 10 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The crystalline penicillin used in making the batch; 3 packages, each containing approximately equal portions of not less than 250 milligrams, packaged in accordance with the requirements of § 146a.24 (b).

(iii) The bacitracin used in making the batch; 3 packages, each containing approximately 0.5 gram packaged in accordance with the requirements of § 146e.401 (b) of this chapter.

(iv) In case of an initial request for certification, each other ingredient used in making the batch; 1 package of each containing approximately 5 grams.

(4) If such batch is packaged for repacking, such person shall submit with his request a sample consisting of the following:

(i) For all tests except sterility; 10 approximately equal portions of at least 2 grams each.

(ii) For sterility testing; 10 approximately equal portions of at least 0.5 gram each.

Each such portion shall be taken from different parts of such batch, and each shall be packaged in a separate container and in accordance with the requirements of paragraph (b) of this section.

(5) No result referred to in subparagraph (2) (ii) and (iii) of this paragraph, and no sample referred to in subparagraph (3) (ii) and (iii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (3) (i) (*a*), (ii), (iii), (iv), and (4) (i) of this section; and

(2) If the Commissioner considers that investigations other than examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.64 *l-Ephenamine penicillin G (penicillin G l-ephenamine salt)*—(a) *Standards of identity, strength, quality and purity.* *l*-Ephenamine penicillin G is the heat stable crystalline *levo*-N-methyl-1, 2-diphenyl-2-hydroxyethylamine salt of penicillin G, prepared from crystalline penicillin G and crystalline *dl*-N-methyl-1, 2-diphenyl-2-hydroxyethylamine hydrochloride (98 percent purity and a melting point of 268.5° C. ±2.5° C.). It contains not less than 85 percent by weight of the *levo*-N-methyl-1, 2-diphenyl-2-hydroxyethylamine salt of penicillin G. It is so purified and dried that:

(1) Its potency is not less than 900 units per milligram;

(2) It is sterile;

(3) It is nonpyrogenic;

(4) It is nontoxic;

(5) Its moisture content is not more than 1.5 percent;

(6) Its pH in a saturated aqueous solution is not less than 5 and not more than 7.5; and

(7) Its specific rotation in water-acetone (1+1) at 20° C. is +125° ±5°.

(b) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its outside wrapper or container and the immediate container as hereinafter indicated, the following:

(1) The batch mark;

(2) The weight of the drug and the number of units in the immediate container;

(3) The statement "Expiration date ------------," the blank being filled in with the date which is 36 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(4) The statement "For manufacturing use only";

(5) The statement "Caution: Federal law prohibits dispensing without prescription."

(d) *Request for certification, check tests and assays; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the weight of the drug and the number of units in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising such batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him for potency, sterility, toxicity, pyrogens, moisture, pH, crystallinity, heat stability, the penicillin G content, and specific rotation.

(2) Such person shall submit with his request an accurately representative sample of the batch, consisting of the following:

(i) For all tests except sterility; 10 packages.

(ii) For sterility testing; 10 packages. Each such package shall contain approximately 300 milligrams taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(3) In connection with contemplated requests for certification of batches of another drug in the manufacture of which it is to be used, the manufacturer of a batch which is to be so used may request the Commissioner to make check tests and assays on a sample of such batch taken as prescribed by subparagraph (2) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drugs. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (2) (i) and (3) of this section; and

(2) If the Commissioner considers that investigations other than the examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.65 *l-Ephenamine penicillin G in oil*—(a) *Standards of identity, strength, quality, and purity.* *l*-Ephenamine penicillin G in oil is a suspension of *l*-ephenamine penicillin G in refined peanut oil or sesame oil with or without the addition of one or more suitable and harmless dispersing agents. Its potency is 300,000 units per milliliter unless it is packaged and labeled solely for veterinary use. It is sterile. Its moisture content is not more than 1 percent. The *l*-ephenamine penicillin G used conforms to the requirements of § 146a.64 (a). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* The immediate container shall be of colorless transparent glass (unless it is packaged to contain a single dose), so closed as to be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, and shall be so sealed that the contents cannot be used without destroying such seal. The immediate container shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. If it is packaged for dispensing, each such container shall contain not less than 1.0 milliliter and not more than 20 milliliters and each shall be filled with a volume in excess of that designated, which excess shall be sufficient to permit the withdrawal and the administration of the volume indicated, whether administered in single or multiple doses.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container of the package:

(i) The batch mark;

(ii) The number of units per milliliter of the batch;

(iii) The statement "Expiration date ------------," the blank being filled in with the date which is 18 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) The statements "For intramuscular use only" and "Shake well"; and

(v) The name of each oil used in making the batch, and, if aluminum monostearate is used as the dispersing agent, the quantity used.

(2) On the outside wrapper or container, the statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing:

(i) If it is intended for use by man, adequate directions and warnings for its use by practitioners licensed by law to administer such drug.

(ii) If it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the *l*-ephenamine penicillin G used in making such batch was completed, the number of units in each of such packages, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that each ingredient used in making such batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph such person shall submit in connection with his request results of tests and assays of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, and moisture.

(ii) The *l*-ephenamine penicillin G used in making the batch; potency, sterility, pyrogens, toxicity, moisture, pH, crystallinity, heat stability, penicillin G content, and specific rotation.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility; one package for each 500 packages in the batch, but in no case less than 3 packages or more than 12 packages.

(*b*) For sterility testing; 10 packages. Such samples shall be collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The *l*-ephenamine penicillin G used in making the batch:

(*a*) For all tests except sterility; 10 packages, each containing approximately equal portions of not less than 300 milligrams.

(*b*) For sterility testing; 10 packages, each containing approximately equal portions of not less than 300 milligrams.

Each such portion shall be packaged in accordance with the requirements of § 146a.64 (b).

(iii) In case of an initial request for certification, one package containing approximately 150 grams of the peanut oil or sesame oil used and one package containing approximately 5 grams of each dispersing agent used.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i) (*a*), (ii) (*a*), and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.66 *l-Ephenamine penicillin G for aqueous injection*—(a) *Standards of identity, strength, quality, and purity. l*-Ephenamine penicillin G for aqueous injection is a dry mixture of *l*-ephenamine penicillin G and one or more suitable and harmless suspending or dispersing agents, with or without one or more suitable and harmless preservatives and buffer substances, or it is an aqueous suspension of *l*-ephenamine penicillin G and one or more suitable and harmless suspending or dispersing agents, buffer substances, and preservatives, except that preservatives are not required if the immediate container is packaged to contain a single dose and is conspicuously so labeled. It is so purified that:

(1) If it is an aqueous suspension of the drug, each container or each milliliter shall contain not less than 300,000 units, unless it is packaged and labeled solely for veterinary use;

(2) It is sterile;

(3) If it is the dry mixture of the drug, its moisture content is not more than 1.5 percent;

(4) It is nonpyrogenic;

(5) It is nontoxic; and

(6) Its pH in saturated aqueous solution is not less than 5.0 and not more than 7.5.

The *l*-ephenamine penicillin G used conforms to the requirements of §146a.64 (a). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing, it shall be in immediate containers of colorless transparent glass, closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness, unless it is the aqueous suspension of the drug and it is packaged to contain a single dose. If it is the dry mixture of the drug, each such container shall contain 300,000 units, 600,000 units, 900,000 units, 1,200,000 units, 1,500,000 units, or 3,000,000 units (unless it is packaged and labeled solely for veterinary use), and each may be packaged in combination with a container of a suitable aqueous diluent. If it is the aqueous suspension of the drug, each such container shall contain not less than 1 milliliter (unless it is packaged to contain a single dose) and not more than 10 milliliters (unless it is packaged and labeled solely for veterinary use), and each shall be filled with a volume in excess of that designated, which excess shall be sufficient to permit the withdrawal and the administration of the volume indicated, whether administered in either single or multiple doses.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in the immediate container;

(iii) The statement "Expiration date ___________," the blank being filled in, if it is the dry mixture of the drug, with the date which is 18 months, or if it is the aqueous suspension of the drug, with the date which is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 24 months after the month in which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) The statement "For intramuscular use only"; and

(v) If the drug contains preservatives, the name and quantity of each preservative used.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is the aqueous suspension of the drug, the statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)," unless the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section after having been stored at room temperature.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing:

(i) If it is intended for use by man, adequate directions and warnings for its use by practitioners licensed by law to administer such drug.

(ii) If it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(iii) If it is the dry mixture of the drug, the conditions under which suspensions made from such drug should be stored, and the statement "Sterile suspension may be kept at room temperature for 1 week, or in refrigerator for 3 weeks, without significant loss of potency."

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of *l*-ephenamine penicillin G for aqueous injection shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the *l*-ephenamine penicillin G used in making such batch was completed, the number of units in each of such packages, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section. If such batch, or any part thereof, is to be packaged with a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (5) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, moisture (unless it is the aqueous suspension of the drug), pyrogens, toxicity, pH.

(ii) The *l*-ephenamine penicillin G used in making the batch; potency, crystallinity, heat stability, penicillin G content, and specific rotation.

(3) Except as otherwise provided by subparagraph (5) of this paragraph, if such batch is packaged for dispensing, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility: one immediate container for each 5,000 immediate containers in such batch, but in no case less than 10 or more than 17 immediate containers.

(*b*) For sterility testing; 10 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The *l*-ephenamine penicillin G used in making the batch; 3 packages containing approximately equal portions of not less than 500 milligrams each, packaged in accordance with the requirements of § 146a.64 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch, one package of each containing approximately 5 grams.

(iv) In case of an initial request for the certification of a batch which is to be packaged in combination with an aqueous diluent which is not recognized by the U. S. P., or when any change is made in the composition of such diluent; 5 packages of the diluent included in the combination.

(4) If such batch is packaged for repacking, such person shall submit with his request a sample consisting of the following:

(i) For all tests except sterility; 10 packages.

(ii) For sterility testing; 10 packages.

Each such package shall contain approximately 300 milligrams taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(5) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (3) (i) (a), (ii), (iii), (iv), and (4) (i) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.67 *Procaine penicillin in streptomycin sulfate solution; procaine penicillin in dihydrostreptomycin sulfate solution (procaine penicillin in crystalline dihydrostreptomycin sulfate solution)*—(a) *Standards of identity, strength, quality, and purity.* Procaine penicillin in streptomycin sulfate solution is procaine penicillin suspended in an aqueous solution of streptomycin sulfate. Procaine penicillin in dihydrostreptomycin sulfate solution is procaine penicillin suspended in an aqueous solution of dihydrostreptomycin sulfate or crystalline dihydrostreptomycin sulfate. Such solution shall contain one or more suitable and harmless buffer substances, preservatives, and suspending or dispersing agents, and it may contain one or more suitable and harmless stabilizing agents and procaine hydrochloride in a concentration not exceeding 2 percent. It is so purified that:

(1) Each milliliter shall contain not less than 100,000 units of procaine penicillin and not less than 0.25 gram of streptomycin sulfate or dihydrostreptomycin sulfate, but each immediate container shall contain not less than 300,000 units of procaine penicillin and not less than 0.25 gram of streptomycin sulfate or dihydrostreptomycin sulfate;

(2) It is sterile;

(3) It is nonpyrogenic;

(4) It is nontoxic; and

(5) Its pH is not less than 5.0 and not more than 8.0.

The procaine penicillin used conforms to the requirements prescribed by § 146a.44 (a). The streptomycin sulfate used conforms to the requirements prescribed by § 146b.101 (a) of this chapter. The dihydrostreptomycin sulfate used conforms to the requirements prescribed by § 146b.106 (a) of this chapter. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing, it shall be in immediate containers of colorless (unless it is intended solely for veterinary use) transparent glass closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness, unless it is packaged to contain a single dose. Each such container shall contain not less than 1 milliliter (unless it is packaged to contain a single dose) and not more than 30 milliliters (unless it is packaged and intended solely for veterinary use), and each shall be filled with a volume in excess of that designated, which excess shall be sufficient to permit the withdrawal and administration of the volume indicated, whether administered in either single or multiple doses.

(c) *Labeling.* Each package shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of units of procaine penicillin and the number of milligrams or grams of streptomycin sulfate or dihydrostreptomycin sulfate in each milliliter of the batch.

(iii) The name and quantity of each preservative used, and if it contains added procaine hydrochloride, the quantity of such added ingredient.

(iv) The statement "Expiration date ----," the blank being filled in with the date which is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 18 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(v) The statement "For intramuscular use only."

(vi) The statement "For manufacturing use," "For repacking," or "For manufacturing use or repacking," when packaged for repacking or for use as an ingredient in the manufacture of another drug, as the case may be.

(2) On the outside wrapper or container:

(i) The statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)."

(ii) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing:

(i) If it is intended for use by man, adequate directions and warnings for its use by practitioners licensed by law to administer such drug.

(ii) If it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the number of units of procaine penicillin and the number of milligrams or grams of streptomycin sulfate or dihydrostreptomycin sulfate in each milliliter of the batch, the batch marks and (unless they were previously submitted) the dates on which the latest assays of the procaine penicillin and streptomycin sulfate or dihydrostreptomycin sulfate used in making such batch were completed, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch, and a statement that each such ingredient conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (5) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, toxicity, pyrogens, pH.

(ii) The procaine penicillin used in making the batch; potency, crystallinity, penicillin K content (unless it is procaine penicillin G), and the penicillin G content if it is procaine penicillin G.

(iii) The streptomycin sulfate or dihydrostreptomycin sulfate used in making the batch; potency, histamine content, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin.

(3) Except as otherwise provided by subparagraph (5) of this paragraph, if such batch is packaged for dispensing, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility; one immediate container for each 5,000 immediate containers in such batch, but in no case less than 12 or more than 19 immediate containers.

(*b*) For sterility testing; 10 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The procaine penicillin used in making the batch; three packages, each containing approximately equal portions of not less than 0.5 gram, packaged in accordance with the requirements of § 146a.44 (b).

(iii) The streptomycin sulfate or dihydrostreptomycin sulfate used in making the batch; three packages, each containing approximately equal portions of not less than 0.5 gram, packaged in accordance with the requirements of § 146b.101 (b) of this chapter.

(iv) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(4) If such batch is packaged for repacking, such person shall submit with his request a sample consisting of:

(i) For all tests except sterility; 12 approximately equal portions of at least 2 milliliters.

(ii) For sterility testing; 10 approximately equal portions of at least 1 milliliter.

Each such portion shall be taken from different parts of such batch, and each shall be packaged in a separate container and in accordance with the requirements of paragraph (b) of this section.

(5) No result referred to in subparagraph (2) (ii) and (iii) of this paragraph, and no sample referred to in subparagraph (3) (ii) and (iii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) (3) (i) (*a*), (ii), (iii), (iv), and (4) (i) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter, for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.68 *Benzathine penicillin G (benzathine penicillin G salt)*—(a) *Standards of identity, strength, quality, and purity.* Benzathine penicillin G is the crystalline N,N'dibenzylethylenediamine salt of penicillin G. It contains not less than 85 percent by weight of the N,N'dibenzylethylenediamine salt of penicillin G. Each such drug is so purified and dried that:

(1) Its potency is not less than 1050 units per milligram.

(2) It is sterile.

(3) It is nontoxic.

(4) It is nonpyrogenic.

(5) Its moisture content is not more than 8 percent.

(6) Its pH in a saturated aqueous solution is not less than 5.0 and not more than 7.5.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its outside wrapper or container and the immediate container, as hereinafter indicated, the following:

(1) The batch mark.

(2) The weight of the drug and the number of units in the immediate container.

(3) The statement "Expiration date -------------," the blank being filled in with the date which is 36 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(4) The statement "For manufacturing use only."

(5) The statement "Caution: Federal law prohibits dispensing without prescription."

(d) *Request for certification, check tests and assays; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the weight of the drug and the number of units in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising such batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, sterility, toxicity, pyrogens, moisture, pH crystallinity, and the penicillin G content.

(2) Such person shall submit with his request an accurately representative sample of the batch, consisting of the following:

(i) For all tests except sterility; 10 packages.

(ii) For sterility testing; 10 packages. Each such package shall contain approximately 300 milligrams taken from different parts of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(3) In connection with contemplated requests for certification of batches of another drug in the manufacture of which benzathine penicillin G is to be used, the manufacturer of a batch which is to be so used may request the Commissioner to make check tests and assays on a sample of such batch, taken as prescribed by subparagraph (2) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) (2) (i) and (3) of this section.

(2) If the Commissioner considers that investigations, other than the examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter, for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.69 *Benzathine penicillin G oral suspension; benzathine penicillin G for oral suspension*—(a) *Standards of identity, strength, quality, and purity.* Benzathine penicillin G oral suspension is an aqueous suspension of benzathine penicillin G, and benzathine penicillin G for oral suspension is a dry mixture of benzathine penicillin G; each drug may contain one or more suitable and harmless dispersing agents, buffer substances, and preservatives, with or without one or more suitable sulfonamides and suitable and harmless colorings and flavorings. The potency of the oral suspension and of the suspension prepared as directed in its labeling is not less than 20,000 units per milliliter. Its pH is not less than 6.0 and not more than 7.0. If it is a dry mixture of the drug, its moisture content is not more than 6.0 percent. The benzathine penicillin G used conforms to the requirements of § 146a.68 (a), except subparagraphs (2), (4), and, if it is the oral suspension, (5) of that paragraph. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* The immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of units in each milliliter of the batch, if it is the oral suspension, and the number of units in each immediate container, if it is a dry mixture.

(iii) The name of each buffer substance and the name and quantity of each sulfonamide and preservative used in making the batch.

(iv) The statement "Shake well."

(v) The statement "Expiration date -----------," the blank being filled in with the date which is 24 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the label and labeling, if sulfonamides are present, after the name "Benzathine penicillin G oral suspension or benzathine penicillin G for oral suspension," wherever it appears, the words "with sulfonamides" in juxtaposition with such name.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the benzathine penicillin G used in making such batch was completed, the potency per milliliter if it is a suspension of the drug and the number of units in each immediate container if it is a dry mixture, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch, and a statement that each such ingredient conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per milliliter if it is the oral suspension, average potency per immediate container if it is a dry mixture, pH, and moisture if it is a dry mixture of the drug.

(ii) The benzathine penicillin G used in making the batch; potency, toxicity, pH, moisture (if it is used in the preparation of a dry mixture), crystallinity, and the penicillin G content.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 or more than 12 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The benzathine penicillin G used in making the batch; 10 packages, each containing approximately equal portions of not less than 300 milligrams, packaged in accordance with the requirements of § 146a.68 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i), (ii), and (iii) of this section.

(2) If the Commissioner considers that investigations, other than the examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.70 *Penicillin-streptomycin-bacitracin ointment; penicillin-dihydrostreptomycin-bacitracin ointment.* (a) Penicillin-streptomycin-bacitracin ointment and penicillin-dihydrostreptomycin-bacitracin ointment conform to all requirements prescribed by § 146a.54 for penicillin-streptomycin ointment and penicillin-dihydrostreptomycin ointment, except that:

(1) It contains not less than 500 units of bacitracin per gram.

(2) In addition to the labeling prescribed by § 146a.54 (b), each package shall bear on the outside wrapper or container and the immediate container the number of units of bacitracin per gram of ointment.

(3) In addition to complying with requirements of § 146a.54 (c) a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless previously submitted) the results and the date of the latest tests and assays of the bacitracin used in making the batch for potency, toxicity, moisture, and pH. He shall also submit in connection with his request a sample consisting of not less than 7 packages of such ointment and (unless it was previously submitted) a sample consisting of 6 packages containing approximately equal portions of not less than 0.5 gram each of the bacitracin used in making the batch, packaged in accordance with the requirements of § 146e.401 (b) of this chapter.

(b) The fee for the services rendered with respect to each immediate container in the sample of bacitracin submitted in accordance with requirements prescribed therefor by this section shall be $4.00.

§ 146a.71 *Penicillin-streptomycin dental cones; penicillin-dihydrostreptomycin dental cones.* (a) Penicillin-streptomycin dental cones and penicillin-dihydrostreptomycin dental cones conform to all requirements prescribed by § 146a.31 for penicillin dental cones and are subject to all procedures prescribed by that section for penicillin dental cones, except that:

(1) Each cone contains not less than 25 milligrams of streptomycin or dihydrostreptomycin. The streptomycin used conforms to the standards prescribed by § 146b.101 (a) of this chapter, except subparagraphs (2), (4), and (5) of that paragraph. The dihydrostreptomycin used conforms to the standards prescribed by § 146b.103 of this chapter, except the standards for sterility, pyrogens, and histamine.

(2) Its moisture content is not more than 3 percent.

(3) In lieu of the labeling prescribed for penicillin dental cones by § 146a.31 (c) (1) (ii), each package shall bear on the outside wrapper or container and the immediate container the number of units of penicillin and the number of milligrams of streptomycin or dihydrostreptomycin in each cone of the batch.

(4) In addition to complying with the requirements of § 146a.31 (d), the person who requests certification of a batch of penicillin-streptomycin dental cones or penicillin-dihydrostreptomycin dental cones shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the streptomycin or dihydrostreptomycin used in making the batch for potency, toxicity, moisture, pH, streptomycin content if it is dihydrostreptomycin and crystallinity if it is crystalline dihydrostreptomycin, and the number of units of penicillin and the number of milligrams of streptomycin or dihydrostreptomycin in each cone of the batch. He shall also submit in connection with his request a sample consisting of not less than 30 cones and (unless it was previously submitted) a sample consisting of 5 packages containing approximately equal portions of not less than 0.5 gram each of the streptomycin or dihydrostreptomycin used in making the batch, packaged in accordance with the requirements of § 146b.101 (b) of this chapter.

(b) The fee for the services rendered with respect to each immediate container in the sample of streptomycin or dihydrostreptomycin submitted in accordance with the requirements prescribed by this section shall be $4.00.

§ 146a.74 *Diethylaminoethyl ester penicillin G hydriodide (penicillin G diethylaminoethyl ester hydriodide)*—(a) *Standards of identity, strength, quality, and purity.* Diethylaminoethyl ester penicillin G hydriodide is the crystalline diethylaminoethyl ester hydriodide salt of penicillin G. It contains not less than 85 percent by weight of β-diethylaminoethyl ester hydriodide salt of penicillin G. It is so purified and dried that:

(1) Its potency after hydrolysis is not less than 900 units per milligram.

(2) It is sterile.

(3) It is nonpyrogenic.

(4) It is nontoxic.

(5) Its moisture content is not more than 1 percent.

(6) The pH of a saturated aqueous solution is not less than 4.0 and not more than 6.5.

(b) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear, on its outside wrapper or container and the immediate container as hereinafter indicated, the following:

(1) The batch mark.

(2) The weight of the drug and the number of units in the immediate container.

(3) The statement "Expiration date ------------," the blank being filled in with the date which is 24 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(4) The statement "For manufacturing use only."

(5) The statement "Caution: Federal law prohibits dispensing without prescription."

(d) *Request for certification, check tests and assays; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the weight of the drug and the number of units in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising such batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him for potency, sterility, toxicity, pyrogens, moisture, pH, crystallinity, and the penicillin G content.

(2) Such person shall submit with his request an accurately representative sample of the batch, consisting of the following:

(i) For all tests except sterility; 10 packages.

(ii) For sterility testing; 10 packages.

Each such package shall contain approximately 300 milligrams taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(3) In connection with contemplated requests for certification of batches of another drug in the manufacture of which it is to be used, the manufacturer of a batch which is to be so used may request the Commissioner to make check tests and assays on a sample of such batch, taken as prescribed by subparagraph (2) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drugs. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (2) (i) and (3) of this section.

(2) If the Commissioner considers that investigations other than the examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter, for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.75 *Diethylaminoethyl ester penicillin G hydriodide for aqueous injection (penicillin G diethylaminoethyl ester hydriodide for aqueous injection)*—(a) *Standards of identity, strength, quality, and purity.* Diethylaminoethyl ester penicillin G hydriodide for aqueous injection is diethylaminoethyl ester penicillin G hydriodide and one or more suitable and harmless suspending or dispersing agents, with or without one or more suitable and harmless preservatives and buffer substances. It is so purified and dried that:

(1) It is sterile.

(2) Its moisture content is not more than 1 percent.

(3) It is nonpyrogenic.

(4) It is nontoxic.

(5) The pH of a saturated aqueous solution is not less than 5.0 and not more than 7.5.

The diethylaminoethyl ester penicillin G hydriodide used conforms to the requirements of § 146a.74 (a). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing, it shall be in immediate containers of colorless transparent glass, closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness. Each such container shall contain 500,000 units or multiples thereof up to and including 5,000,000 units, and each may be packaged in combination with a container of a suitable aqueous diluent.

(c) *Labeling.* Each package shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of units in the immediate container.

(iii) The statement "Expiration date ____________," the blank being filled in with the date which is 24 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(iv) The statement "For intramuscular use only."

(2) On the outside wrapper or container, the statement "Caution: Federal law prohibits dispensing without prescription," unless it is intended solely for veterinary use and is conspicuously so labeled.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing:

(i) If it is intended for use by man, adequate directions and warnings for its use by practitioners licensed by law to administer such drug.

(ii) If it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(iii) The conditions under which suspensions of the drug may be stored, and the statement "Sterile suspension may be kept at room temperature for 7 days, or in refrigerator for 3 weeks, without significant loss of potency."

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the diethylaminoethyl ester penicillin G hydriodide used in making such batch was completed, the number of units in each such packages, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section. If such batch, or any part thereof, is to be packaged with a solvent, such request shall be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (5) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, moisture, pyrogens, toxicity, pH.

(ii) The diethylaminoethyl ester penicillin G hydriodide used in making the batch; potency, crystallinity, penicillin G content.

(3) Except as otherwise provided by subparagraph (5) of this paragraph, if such batch is packaged for dispensing such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility; one immediate container for each 5,000 immediate containers in such batch, but in no case less than 10 or more than 17 immediate containers.

(*b*) For sterility testing; 10 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The diethylaminoethyl ester penicillin G hydriodide used in making the batch; 3 packages containing approximately equal portions of not less than 500 milligrams each, packaged in accordance with the requirements of § 146a.74 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(iv) In the case of an initial request for the certification of a batch which is to be packaged in combination with an aqueous diluent which is not recognized by the U. S. P., or when any change is made in the composition of such diluent; 5 packages of the diluent included in the combination.

(4) If such batch is packaged for repacking, such person shall submit with his request a sample consisting of the following:

(i) For all tests except sterility; 10 packages.

(ii) For sterility testing; 10 packages. Each such package shall contain approximately 300 milligrams, taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(5) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (3) (i) (*a*), (ii), (iii), (iv), and (4) (i) of this section.

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter, for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.76 *Penicillin-streptomycin implantation pellets; penicillin-dihydrostreptomycin implantation pellets*—(a) *Standards of identity, strength, quality, and purity.* Penicillin-streptomycin implantation pellets and penicillin-dihydrostreptomycin implantation pellets are pellets composed of crystalline penicillin or procaine penicillin and streptomycin or dihydrostreptomycin, with or without the addition of one or more suitable and harmless diluents, binders, and lubricants. Each pellet contains not less than 5,000 units of penicillin and not less than 6.25 milligrams of streptomycin or dihydrostreptomycin. Its moisture content is not more than 5 percent. The crystalline penicillin conforms to the requirements of § 146a.24 (a), except subparagraphs (2) and (4) of that paragraph. The procaine penicillin conforms to the requirements of § 146a.44 (a), except subparagraphs (2) and (3) of that paragraph. The streptomycin used conforms to the requirements of § 146b.101 (a) of this chapter, except subparagraphs (2) and (4) of that paragraph. The dihydrostreptomycin used conforms to the requirements prescribed therefor by § 146b.103 of this chapter, except the standards for sterility and pyrogens. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the requirements prescribed therefor by such official compendium.

(b) *Packaging.* Unless each pellet is enclosed in a foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the pellets by a plug of cotton or other like material. The composition of the immediate container or of the foil or film enclosure shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of units of penicillin in each pellet of the batch.

(iii) The number of milligrams of streptomycin or dihydrostreptomycin in each pellet of the batch.

(iv) The statement "For veterinary use only."

(v) The statement "Expiration date ____________," the blank being filled in with the date which is 18 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the circular or other labeling within or attached to the package, if it is packaged for dispensing, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch marks and (unless they were previously submitted) the dates on which the latest assays of the penicillin and streptomycin or dihydrostreptomycin used in making the batch were completed, the number of units of penicillin and the number of milligrams of streptomycin or dihydrostreptomycin in each pellet, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch, and a statement that each such ingredient conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, moisture.

(ii) The penicillin used in making the batch; potency, toxicity, moisture, pH, crystallinity, and heat stability (unless it is procaine penicillin), penicillin K content (unless it is crystalline penicillin G or procaine penicillin G), and the penicillin G content if it is crystalline penicillin G or procaine penicillin G.

(iii) The streptomycin or dihydrostreptomycin used in making the batch; potency, toxicity, histamine content, moisture, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin sulfate.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one pellet for each 5,000 pellets in the batch, but in no case less than 30 pellets or more than 100 pellets, collected by taking single pellets at such intervals throughout the entire time of tableting the batch that the quantities tableted during the intervals are approximately equal.

(ii) The penicillin used in making the batch; 10 packages, each containing approximately equal portions of not less than 60 milligrams if it is crystalline penicillin and not less than 300 milligrams if it is procaine penicillin, each taken from a different part of such batch and packaged in accordance with the requirements of § 146a.24 (b) or § 146a.44 (b).

(iii) The streptomycin or dihydrostreptomycin used in making the batch; 5 packages, each containing approximately 0.5 gram, taken from a different part of such batch and packaged in accordance with the requirements of § 146b.101 (b) of this chapter.

(iv) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) and (iii) of this paragraph, and no sample referred to in subparagraph (3) (ii) and (iii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fees for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $1.00 for each pellet in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iv) of this section; $10.00 for each package in the sample submitted in accordance with paragraph (d) (3) (iii) of this section.

(2) If the Commissioner considers that investigations other than examination of such pellets and packages are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter, for the

issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.77 *Benzathine penicillin G for aqueous injection*—(a) *Standards of identity, strength, quality, and purity.* Benzathine penicillin G for aqueous injection is a dry mixture of benzathine penicillin G and one or more suitable and harmless suspending or dispersing agents and with or without one or more suitable and harmless preservatives, buffer substances, and local anesthetics; or it is an aqueous suspension of benzathine penicillin G and one or more suitable and harmless suspending or dispersing agents, buffer substances, and preservatives and with or without one or more suitable and harmless local anesthetics. It is so purified that:

(1) If it is an aqueous suspension of the drug, each container or each milliliter shall contain not less than 300,000 units.

(2) It is sterile.

(3) If it is the dry mixture of the drug, its moisture content is not more than 8 percent.

(4) It is nonpyrogenic.

(5) It is nontoxic.

(6) Its pH in saturated solution is not less than 5.0 and not more than 7.5.

The benzathine penicillin G used conforms to the requirements of § 146a.68 (a). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing, it shall be in immediate containers of colorless, (unless it is intended solely for veterinary use) transparent glass, closed by a substance through which a hyprodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness. If it is the dry mixture of the drug, each such container shall contain 300,000 units, 600,000 units, 900,000 units, 1,200,000 units, 1,500,000 units, 2,400,000 units, or 3,000,000 units, unless it is intended solely for veterinary use and is conspicuously so labeled. Each such container may be packaged in combination with a container of a suitable aqueous diluent. If it is the aqueous suspension of the drug, each such container shall contain not less than 1 milliliter (unless it is packaged to contain a single dose) and not more than 10 milliliters (unless it is intended solely for veterinary use and is conspicuously so labeled), and each shall be filled with a volume in excess of that designated, which excess shall be sufficient to permit the withdrawal and the administration of the volume indicated, whether administered in either single or multiple doses.

(c) *Labeling.* Each package shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of units in the immediate container.

(iii) The statement "Expiration date ____________," the blank being filled in, if it is a dry mixture of the drug, with the date which is 48 months, or if it is the aqueous suspension of the drug, with the date which is 18 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 24 months after the month during which the batch was certified, if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section: *Provided, however,* that such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(iv) The statement "For intramuscular use only."

(v) If the drug contains preservatives or anesthetics, the name and quantity of each such added ingredient.

(2) On the outside wrapper or container:

(i) If it is the aqueous suspension of the drug, the statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)," unless the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section after having been stored at room temperature.

(ii) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing:

(i) If it is intended for use by man, adequate directions and warnings for its use by practitioners licensed by law to administer such drug.

(ii) If it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(iii) If it is the dry mixture of the drug, the conditions under which suspensions made from such drug should be stored, and the statement "Sterile suspension may be kept at room temperature for 1 week, or in refrigerator for 3 weeks, without significant loss of potency."

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of benzathine penicillin G for aqueous injection shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the benzathine penicillin G used in making such batch was completed, the number of units in each of such packages, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section. If such batch, or any part thereof, is to be packaged with a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (5) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, moisture (unless it is an aqueous suspension of the drug), pyrogens, toxicity, pH.

(ii) The benzathine penicillin G used in making the batch; potency, penicillin G content, crystallinity.

(3) Except as otherwise provided by subparagraph (5) of this paragraph, if such batch is packaged for dispensing, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility; one immediate container for each 5,000 immediate containers in such batch, but in no case less than 10 or more than 17 immediate containers.

(*b*) For sterility testing; 10 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The benzathine penicillin G used in making the batch; three packages containing approximately equal portions of not less than 500 milligrams each, packaged in accordance with the requirements of § 146a.68 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(iv) In case of an initial request for the certification of a batch of benzathine penicillin G for aqueous injection which is to be packaged in combination with an aqueous diluent which is not recognized by the U. S. P., or when any change is made in the composition of such diluent, five packages of the diluent included in the combination.

(4) If such batch is packaged for repacking, such person shall submit with his request a sample consisting of the following:

(i) For all tests except sterility; 10 packages.

(ii) For sterility testing; 10 packages. Each such package shall contain not less than approximately 300 milligrams taken from different parts of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(5) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (3) (i) (*a*), (*ii*), (*iii*), (iv), and (4) (i) of this section.

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter, for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.78 *Benzathine penicillin G and buffered crystalline penicillin for aqueous injection.* (a) Benzathine penicillin G and buffered crystalline penicillin for aqueous injection conforms to all requirements prescribed by § 146a.77 for the dry mixture of penicillin G for aqueous injection, and is subject to all procedures prescribed by § 146a.77 for the dry mixture of benzathine penicillin G for aqueous injection, except that:

(1) Each immediate container shall contain not less than 50,000 units of buffered crystalline penicillin for each 300,000 units of benzathine penicillin G. The buffered crystalline penicillin conforms to the requirements prescribed therefor by § 146a.37.

(2) In lieu of the labeling prescribed for benzathine penicillin G for aqueous injection by § 146a.77 (c) (1) (ii), each package shall bear, on the outside wrapper or container and the immediate container, the number of units of benzathine penicillin G and the number of units of buffered crystalline penicillin in the immediate container. The circular or other labeling within or attached to the package, if it is packaged for dispensing, shall bear, in lieu of the statement prescribed by § 146a.77 (c) (3) (iii), the statement "Sterile suspension may be kept in refrigerator for 1 week without significant loss of potency."

(3) In addition to complying with the requirements of § 146a.77 (d), a person who requests certification of a batch of benzathine penicillin G and buffered crystalline penicillin for aqueous injection shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and date of the latest tests and assays of the buffered crystalline penicillin used in making the batch for potency, crystallinity, heat stability, penicillin K content (unless it is buffered crystalline penicillin G) and the penicillin G content if it is buffered crystalline penicillin G, the number of units of benzathine penicillin G and the number of units of buffered crystalline penicillin in each immediate container of the batch. He shall also submit in connection with his request a sample consisting of three packages containing approximately equal portions of not less than 250 milligrams each of the buffered crystalline penicillin used in making the batch. If such batch is packaged for repacking, each portion in the sample required by § 146a.77 (d) (4) shall consist of approximately 400 milligrams in lieu of 300 milligrams.

(b) The fee for the services rendered with respect to each immediate container in the sample of buffered crystalline penicillin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146a.79 *Chloroprocaine penicillin O (penicillin O chloroprocaine salt)*—(a) *Standards of identity, strength, quality, and purity.* Chloroprocaine penicillin O is the crystalline 2-chloroprocaine salt of penicillin O prepared from 2-chloroprocaine hydrochloride (95 percent purity and a melting point of 171°–176° C.) and crystalline penicillin O. It contains not less than 85 percent of the 2-chloroprocaine salt of penicillin O and not more than 0.5 percent of the 2-chloroprocaine salt of penicillin G. Each such drug is so purified and dried that:

(1) Its potency is not less than 850 units per milligram.

(2) It is sterile.

(3) It is nonpyrogenic.

(4) It is nontoxic.

(5) Its moisture content is not more than 4.2 percent.

(6) Its pH in saturated aqueous solution is not less than 5.0 and not more than 7.5.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of chloroprocaine penicillin O shall bear on its outside wrapper or container and the immediate container, as hereinafter indicated, the following:

(1) The batch mark.

(2) The weight of the drug and the number of units in the immediate container.

(3) The statement "Expiration date ____________," the blank being filled in with the date which is 36 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(4) The statement "For manufacturing use only."

(5) The statement "Caution: Federal law prohibits dispensing without prescription."

(d) *Request for certification, check tests and assays; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of chloroprocaine penicillin O shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the weight of the drug and the number of units in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, sterility, toxicity, pyrogens, moisture, pH, crystallinity, chloroprocaine penicillin O content, and chloroprocaine penicillin G content.

(2) Such person shall submit in connection with his request an accurately representative sample of the batch:

(i) For all tests except sterility; 10 packages.

(ii) For sterility testing; 10 packages. Each such package shall contain approximately 300 milligrams taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(3) In connection with contemplated requests for certification of batches of another drug in the manufacture of which chloroprocaine penicillin O is to be used, the manufacturer of a batch which is so used may request the Commissioner to make check tests and assays on a sample of such batch taken as prescribed by subparagraph (2) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (2) (i) and (3) of this section.

(2) If the Commissioner considers that investigations other than the examination of such immediate containers

are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter, for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.80 *Chloroprocaine penicillin O for aqueous injection*—(a) *Standards of identity, strength, quality, and purity.* Chloroprocaine penicillin O for aqueous injection is a dry mixture of chloroprocaine penicillin O and one or more suitable and harmless suspending or dispersing agents, with or without one or more suitable and harmless buffer substances. It is so purified and dried that:

(1) It is sterile.

(2) Its moisture content is not more than 4.2 percent.

(3) It is nonpyrogenic.

(4) It is nontoxic.

(5) Its pH in saturated aqueous solution is not less than 5.0 and not more than 7.5.

The chloroprocaine penicillin O used conforms to the requirements of § 146a.79 (a). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing, it shall be in immediate containers of colorless, transparent glass, closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness. Each such container shall contain 300,000 units, 600,000 units, 900,000 units, 1,200,000 units, 1,500,000 units, or 3,000,000 units, unless it is intended solely for veterinary use and is conspicuously so labeled. Each such container may be packaged in combination with a container of a suitable aqueous diluent.

(c) *Labeling.* Each package shall bear, on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of units in the immediate container.

(iii) The statement "Expiration date ____________," the blank being filled in with the date which is 36 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(iv) The statement "For intramuscular use only."

(2) On the outside wrapper or container, the statement "Caution: Federal law prohibits dispensing without prescription," unless it is intended solely for veterinary use and is conspicuously so labeled.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing:

(i) If it is intended for use by man, adequate directions and warnings for its use by practitioners licensed by law to administer such drug.

(ii) If it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(iii) The conditions under which suspensions made from such drug should be stored, and the statement "Sterile suspension may be kept at room temperature for 1 week, or in refrigerator for 3 weeks, without significant loss of potency."

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of chloroprocaine penicillin O for aqueous injection shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the chloroprocaine penicillin O used in making such batch was completed, the number of units in each of such packages, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section. If such batch, or any part thereof, is to be packaged with a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (5) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, moisture, pyrogens, toxicity, pH.

(ii) The chloroprocaine penicillin O used in making the batch; potency crystallinity, penicillin O content, and penicillin G content.

(3) Except as otherwise provided by subparagraph (5) of this paragraph, if such batch is packaged for dispensing, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility; one immediate container for each 5,000 immediate containers in such batch, but in no case less than 10 or more than 17 immediate containers.

(*b*) For sterility testing; 10 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The chloroprocaine penicillin O used in making the batch: six packages containing approximately equal portions of not less than 300 milligrams each.

(iii) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5.0 grams.

(iv) In case of an initial request for the certification of a batch of chloroprocaine penicillin O for aqueous injection which is to be packaged in combination with an aqueous diluent which is not recognized by the U. S. P., or when any change is made in the composition of such diluent, five packages of the diluent included in the combination.

(4) If such batch is packaged for repacking, such person shall submit with his request a sample consisting of the following:

(i) For all tests except sterility; 10 packages.

(ii) For sterility testing; 10 packages. Each such package shall contain not less than approximately 300 milligrams taken from different parts of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(5) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraphs (d) (3) (i) (*a*), (ii), (iii), and (iv) and (4) (i) of this section.

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.81 *Penicillin-streptomycin vaginal suppositories; penicillin-dihydro-*

streptomycin vaginal suppositories. (a) Penicillin-streptomycin vaginal suppositories and penicillin-dihydrostreptomycin vaginal suppositories conform to all requirements prescribed by § 146a.36 for penicillin vaginal suppositories and are subject to all procedures prescribed by that section for penicillin vaginal suppositories, except that:

(1) Each suppository shall contain not less than 200 milligrams of streptomycin or dihydrostreptomycin. The streptomycin used conforms to the standards prescribed by § 146b.101 (a) of this chapter, except subparagraphs (2), (4), and (5) of that paragraph. The dihydrostreptomycin used conforms to the standards prescribed by § 146b.103 of this chapter except the standards for sterility, pyrogens, and histamine.

(2) In lieu of the labeling prescribed for penicillin vaginal suppositories by § 146a.36 (c) (1) (ii), each package shall bear on the outside wrapper or container and the immediate container the number of units of penicillin and the number of milligrams of streptomycin or dihydrostreptomycin in each suppository of the batch.

(3) In addition to complying with the requirements of § 146a.36 (d), a person who requests certification of a batch of penicillin-streptomycin vaginal suppositories or penicillin-dihydrostreptomycin vaginal suppositories shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the streptomycin or dihydrostreptomycin used in making the batch for potency, toxicity, moisture, pH, streptomycin content if it is dihydrostreptomycin and crystallinity if it is crystalline dihydrostreptomycin, and the number of units of penicillin and the number of milligrams of streptomycin or dihydrostreptomycin in each suppository in the batch. He shall also submit in connection with his request a sample consisting of not less than 30 suppositories and (unless it was previously submitted) a sample consisting of 5 packages containing approximately equal portions of not less than 0.5 gram each of the streptomycin or dihydrostreptomycin used in making the batch, packaged in accordance with the requirements of § 146b.101 (b) of this chapter.

(b) The fee for the services rendered with respect to each immediate container in the sample of streptomycin or dihydrostreptomycin submitted in accordance with the requirements prescribed by this section shall be $4.00.

§ 146a.82 *Penicillin-streptomycin-bacitracin dental paste; penicillin-dihydrostreptomycin-bacitracin dental paste*—(a) *Standards of identity, strength, quality, and purity.* Penicillin-streptomycin-bacitracin dental paste and penicillin - dihydrostreptomycin - bacitracin dental paste is calcium penicillin, crystalline sodium or potassium penicillin, or procaine penicillin, streptomycin or dihydrostreptomycin, bacitracin, and sodium caprylate in a suitable and harmless base. Its moisture content is not more than 2 percent. It contains not less than 200,000 units of penicillin, not less than 2,000 units of bacitracin, and not less than 0.20 gram of streptomycin or dihydrostreptomycin per milliliter. The calcium penicillin or crystalline penicillin used conforms to the requirements of § 146a.24 (a) except the limitation on penicillin K content, and except subparagraphs (1) and (4) of that paragraph, but its potency is not less than 300 units per milligram. The procaine penicillin used conforms to the requirements of § 146a.44 (a) except subparagraph (3) of that paragraph. The streptomycin used conforms to the standards prescribed by § 146b.101 (a) of this chapter except subparagraphs (4) and (5) of that paragraph. The dihydrostreptomycin used conforms to the standards prescribed by § 146b.103 of this chapter except the standards for pyrogens and histamine. The bacitracin used conforms to the standards prescribed therefor by § 146e.401 (a) of this chapter except subparagraphs (1) and (4) of that paragraph, but its potency is not less than 30 units per milligram.

(b) *Packaging.* The drug shall be packaged in immediate containers of transparent glass which meet the test for tight containers as defined by the U. S. P. Each such glass container shall be so sealed that the contents cannot be used without destroying such seal and shall be closed by a substance through which a hypodermic needle may be introduced and withdrawn without destroying its effectiveness. The immediate container and closure shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of the drug shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of units of penicillin and bacitracin, the number of milligrams of streptomycin or dihyrdostreptomycin, and the quantity of sodium caprylate in each milliliter of the batch.

(iii) The statement "For endodontic use only."

(iv) The statement "Expiration date ----------," the blank being filled in with the date which is not more than 12 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 18 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug as prepared by him is stable for such period of time: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container, the statement "Caution: Federal law prohibits dispensing without prescription."

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing, adequate directions and warnings for its use by practitioners licensed by law to administer such drug.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of penicillin-streptomycin-bacitracin dental paste or penicillin-dihydrostreptomycin-bacitracin dental paste shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark, and (unless they were previously submitted) the dates of the latest tests and assays of the penicillin, streptomycin or dihydrostreptomycin, and bacitracin used in making the batch.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, and moisture.

(ii) The penicillin used in making the batch; potency, toxicity, sterility, moisture, pH, crystallinity if it is crystalline penicillin, heat stability if it is crystalline sodium or potassium penicillin, the penicilln G content if it is crystalline sodium or potassium penicillin G, and the procaine penicillin G content if it is procaine penicillin G.

(iii) The streptomycin or dihydrostreptomycin used in making the batch; potency, toxicity, sterility, moisture, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin sulfate.

(iv) The bacitracin used in making the batch; potency, toxicity, sterility, moisture, and pH.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility; one package for each 500 packages in the batch, but in no case less than 5 packages or more than 12 packages.

(*b*) For sterility testing; 10 packages. Such samples shall be collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The penicillin used in making the batch:

(*a*) For all tests except sterility; 5 packages, or in the case of crystalline penicillin, 10 packages, each containing approximately equal portions of not less than 60 milligrams if it is not procaine penicillin, and not less than 300 milligrams if it is procaine penicillin.

(*b*) For sterility testing; 10 packages, each containing approximately equal portions of 300 milligrams.

Such samples shall be packaged in accordance with the requirements of § 146a.24 (b) or § 146a.44 (b).

(iii) The streptomycin or dihydrostreptomycin used in making the batch:

(*a*) For all tests except sterility; 5 packages containing approximately equal portions of not less than 0.5 gram.

(*b*) For sterility testing; 10 packages, each containing approximately equal portions of 0.5 gram.

Such samples shall be packaged in accordance with the requirements of § 146b.101 (b) of this chapter.

(iv) The bacitracin used in making the batch:

(*a*) For all tests except sterility; 6 packages, each containing approximately equal portions of not less than 0.5 gram.

(*b*) For sterility testing; 10 packages, each containing approximately equal portions of 0.5 gram.

Such samples shall be packaged in accordance with the requirements of § 146e.401 (b) of this chapter.

(v) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii), (iii), and (iv) of this paragraph, and no sample referred to in subparagraph (3) (ii), (iii), and (iv) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of penicillin-streptomycin-bacitracin dental paste or penicillin-dihydrostreptomycin-bacitracin dental paste under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i) (*a*), (ii) (*a*), (iii) (*a*), (iv) (*a*), and (v) of this section.

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.84 *Penicillin and dihydrostreptomycin-streptomycin sulfates, procaine penicillin in dihydrostreptomycin-streptomycin sulfates solution*—(a) *Standards of identity, strength, quality, and purity.* Penicillin and dihydrostreptomycin-streptomycin sulfates and procaine penicillin in dihydrostreptomycin-streptomycin sulfates solution conform to the standards prescribed by § 146b.113 (a) of this chapter for dihydrostreptomycin-streptomycin sulfates, except that:

(1) It contains dry procaine penicillin, benzathine penicillin G, crystalline sodium penicillin or potassium penicillin, or a mixture of any combination of such salts, or it contains procaine penicillin suspended in an aqueous solution of dihydrostreptomycin-streptomycin sulfates. The procaine penicillin used conforms to the requirements prescribed by § 146a.44 (a). The crystalline penicillin used conforms to the requirements prescribed for crystalline penicillin by § 146a.24 (a) The benzathine penicillin G used conforms to the requirement prescribed by § 146a.68 (a).

(2) It may contain suitable and harmless buffer substances, preservatives, suspending, dispersing, and stabilizing agents. Each such substance, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(3) The moisture content of the dry mixture is not more than 3.5 percent, except if it contains procaine penicillin its moisture content is not more than 4.2 percent, and if it contains benzathine penicillin G its moisture content is not more than 6 percent.

(4) The pH of a solution or a suspension prepared as directed in its labeling is not less than 5.0 and not more than 7.5.

(b) *Packaging.* It shall be packaged in accordance with the requirements prescribed by § 146b.113 (b) of this chapter, except that each immediate container or each milliliter shall contain not less than 300,000 units of penicillin, 0.15 gram dihydrostreptomycin, and 0.15 gram streptomycin.

(c) *Labeling.* If it is the dry mixture, it shall be labeled in accordance with the requirements prescribed by § 146a.58 (c), except that each package shall bear on the outside wrapper or container and the immediate container the number of units of each salt of penicillin, the number of grams of dihydrostreptomycin, and the number of grams of streptomycin in the immediate container. If it is the suspension of the drug, it shall be labeled in accordance with the requirements prescribed by § 146a.67 (c), except that each package shall bear on the outside wrapper or container and the immediate container the number of units of procaine penicillin, the number of grams of dihydrostreptomycin, and the number of grams of streptomycin in each milliliter in the immediate container.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146b.113 (d) (1) of this chapter, a person who requests certification of a batch shall submit a statement showing the dates on which the latest assays of the penicillin used in making the batch were completed (unless they were previously submitted), the batch marks, and the content of each salt of penicillin in each container.

(2) Except as otherwise provided by subparagraph (5) of this paragraph, such person shall submit in connection with his request, results of the tests and assays listed after each of the following made by him on an accurately representative sample of:

(i) The batch; content of each salt of penicillin, content of dihydrostreptomycin and streptomycin, sterility, toxicity, pyrogens, moisture (if it is the dry mixture), and pH.

(ii) The procaine penicillin used in making the batch; potency, crystallinity, penicillin K content (unless it is penicillin G) and the penicillin G content if it is procaine penicillin G.

(iii) The crystalline sodium or potassium penicillin used in making the batch; potency, crystallinity, heat stability, pencillin K content (unless it is crystalline penicillin G), and the penicillin G content if it is crystalline penicillin G.

(iv) The benzathine penicillin G used in making the batch; potency, crystallinity, and penicillin G content.

(v) The dihydrostreptomycin and streptomycin used in making the batch; potency, histamine content, and crystallinity if it is crystalline dihydrostreptomycin.

(3) Except as otherwise provided by subparagraph (5) of this paragraph, if such batch is packaged for dispensing such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility; one immediate container for each 5,000 immediate containers in such batch, but in no case less than 13 (14, if it contains benzathine penicillin G) or more than 19 immediate containers.

(*b*) For sterility testing: 10 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The procaine penicillin used in making the batch; 3 packages containing approximately equal portions of not less than 0.5 gram, each packaged in accordance with the requirements of § 146a.44 (b).

(iii) The crystalline penicillin used in making the batch; 3 packages containing approximately equal portions of not less than 250 milligrams, each packaged in accordance with the requirements of § 146a.24 (b).

(iv) The benzathine penicillin G used in making the batch; 3 packages containing approximately equal portions of not less than 0.5 gram each, packaged in accordance with the requirements of § 146a.68 (b).

(v) The dihydrostreptomycin and streptomycin used in making the batch; 3 packages of each salt containing approximately equal portions of not less than 0.5 gram, each packaged in accordance with the requirements of § 146b.101 (b) of this chapter.

(vi) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5.0 grams.

(4) If such batch is packaged for repacking such person shall submit with his request a sample consisting of the following:

(i) For all tests except sterility; 13 (14, if it contains benzathine penicillin G) approximately equal portions of at least 2.0 grams.

(ii) For sterility testing; 10 approximately equal portions of at least 0.5 gram.

Each such portion shall be taken from a different part of such batch and each shall be packaged in a separate container and in accordance with the requirements of paragraph (b) of this section.

(5) No result referred to in subparagraph (2) (ii), (iii), (iv), and (v) of this paragraph, and no sample referred to in subparagraph (3) (ii), (iii), (iv), and (v) of this paragraph is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) (3) (i) (*a*), (ii), (iii), (iv), (v), and (vi) and (4) (i) of this section; and

(2) If the Commissioner considers that investigations other than examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigation.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.85 *Benzathine procaine-buffered crystalline penicillins for aqueous injection.* Benzathine - procaine - buffered crystalline penicillins for aqueous injection conforms to all requirements prescribed by § 146a.50 for procaine penicillin and buffered crystalline penicillin for aqueous injection, except paragraph (b) of that section and is subject to all procedures prescribed by § 146a.50 for procaine penicillin and buffered crystalline penicillin for aqueous injection, except that:

(a) Each immediate container shall contain not less than 200,000 units of benzathine penicillin G, 200,000 units of procaine penicillin, and 100,000 units of buffered crystalline penicillin. The benzathine penicillin G used conforms to the requirements prescribed therefor by § 146a.68.

(b) Its moisture content is not more than 6 percent.

(c) Each package shall bear on the outside wrapper or container and the immediate container the number of units of benzathine penicillin G in the immediate container, and its expiration date shall be 36 months after the month during which the batch was certified.

(d) In addition to complying with the requirements of § 146a.50 (d), a person who requests certification of a batch of benzathine procaine-buffered crystalline penicillins for aqueous injection shall submit with his request a statement showing the batch mark, and (unless it was previously submitted) the results and the date of the latest tests and assays of the benzathine penicillin G used in making the batch for potency, crystallinity, and penicillin G content, and the number of units of benzathine penicillin G in each container of the batch. He shall also submit in connection with his request a sample consisting of three packages containing approximately equal portions of not less than 0.5 gram each of the benzathine penicillin G used in making the batch. If such batch is packaged for repacking, each portion in the sample required by § 146a.50 (d) shall consist of approximately 0.5 gram in lieu of 400 milligrams.

(e) The fee for the services rendered with respect to each immediate container in the sample of benzathine penicillin G submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146a.86 *Benzathine penicillin G and procaine penicillin for aqueous injection.* Benzathine penicillin G and procaine penicillin for aqueous injection conforms to all requirements, and is subject to all procedures, prescribed by § 146a.77 for benzathine penicillin G for aqueous injection, except that:

(a) Each container shall contain not less than 300,000 units of benzathine penicillin G and not less than 300,000 units of procaine penicillin. The procaine penicillin used conforms to the requirements prescribed therefor by § 146a.44 (a).

(b) If it is the dry mixture of the drug, its moisture content is not more than 6.0 percent.

(c) In lieu of the directions for labeling prescribed by § 146a.77 (c) (1) (ii) and (iii), each package shall bear on the outside wrapper or container and the immediate container the number of units of benzathine penicillin G and the number of units of procaine penicillin in each milliliter in the immediate container if it is the aqueous suspension of the drug, or the number of units of benzathine penicillin G and the number of units of procaine penicillin in the immediate container if it is the dry mixture of the drug, and the statement, "Expiration date __________," the blank being filled in, if it is the aqueous suspension of the drug, with the date which is 18 months or, if it is the dry mixture of the drug with the date which is 36 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(d) In addition to complying with the requirements of § 146a.77 (d), a person who requests certification of a batch of benzathine penicillin G and procaine penicillin for aqueous injection shall submit with his request a statement showing the batch mark, and (unless it was previously submitted) the results and the date of the latest tests and assays of the procaine penicillin used in making the batch for potency, crystallinity, penicillin K content (unless it is procaine penicillin G) and the penicillin G content if it is procaine penicillin G, and the number of units of procaine penicillin in each milliliter of the batch, if it is the aqueous suspension of the drug, or the number of units of procaine penicillin in each package of the batch, if it is the dry mixture of the drug. He shall also submit in connection with his request a sample consisting of three packages containing approximately equal portions of not less than 500 milligrams each of the procaine penicillin used in making the batch. If such batch is packaged for repacking, each portion in the sample required by § 146a.77 (d) (4) (i) shall consist of the equivalent of approximately 600 milligrams in lieu of 300 milligrams.

(e) The fee for the services rendered with respect to each immediate container in the sample of procaine penicillin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146a.87 *Penicillin-bacitracin-neomycin ointment; penicillin-bacitracin-neomycin in oil.* Penicillin-bacitracin-neomycin ointment and penicillin-bacitracin-neomycin in oil conform to all requirements prescribed by § 146a.56 for penicillin-bacitracin ointment and are subject to all procedures prescribed by § 146a.56 for penicillin-bacitracin ointment, except that:

(a) It contains not less than 5.0 milligrams of neomycin and not less than 250 units of bacitracin per gram, unless it is packaged and labeled solely for veterinary use. The neomycin used conforms to the standards prescribed by § 146e.410 (a) (2) of this chapter.

(b) In addition to the directions for labeling prescribed for penicillin-bacitracin ointment by § 146a.56 (a) (3), each package shall bear on the outside wrapper or container and the immediate container the number of milligrams of neomycin per gram.

(c) In addition to complying with the requirements of § 146a.56 (a) (4), a person who requests certification of a batch of penicillin-bacitracin-neomycin ointment or penicillin-bacitracin-neomycin in oil shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and dates of the latest tests and assays of the neomycin used in making the batch for potency, toxicity, moisture, and pH. He shall also submit in connection with his request a sample consisting of not less than seven immediate containers of the batch and (unless it was previously submitted) a sample consisting of five packages of the neomycin used in making the batch, containing approximately 0.5 gram each.

(d) The fee for the services rendered with respect to each container in the sample of neomycin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146a.88 *Penicillin-streptomycin tablets; penicillin - dihydrostreptomycin tablets.* (a) Penicillin-streptomycin tablets and penicillin-dihydrostreptomycin tablets conform to all requirements and are subject to all procedures prescribed by § 146a.27 for penicillin tablets, except that:

(1) Each tablet contains not less than 20 milligrams of streptomycin or dihydrostreptomycin. The streptomycin used conforms to the standards prescribed therefor by § 146b.101 (a) of this chapter except subparagraphs (2) and (4) of that paragraph or § 146b.114 (a) of this chapter, if the tablets are intended solely for veterinary use. The dihydrostreptomycin used conforms to the standards prescribed therefor by § 146b.103 of this chapter except the standards for sterility and pyrogens.

(2) In lieu of the labeling prescribed for penicillin tablets by § 146a.27 (c) (1) (ii) and (vi), each package shall bear on the outside wrapper or container and the immediate container the number of units of penicillin and the number of milligrams of streptomycin or dihydrostreptomycin in each tablet and the statement "Expiration date ________," the blank being filled in with the date which is 18 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(3) In addition to complying with the requirements of § 146a.27 (d), a person who requests certification of a batch of penicillin-streptomycin tablets or penicillin-dihydrostreptomycin tablets shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the streptomycin or dihydrostreptomycin used in making the batch for potency, toxicity, histamine content, moisture, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin, and the number of milligrams of streptomycin or dihydrostreptomycin in each tablet of the batch. He shall also submit in connection with his request a sample consisting of not less than 30 tablets and (unless it was previously submitted) a sample consisting of five packages containing approximately equal portions of not less than 0.5 gram each of the streptomycin or dihydrostreptomycin used in making the batch, packaged in accordance with the requirements of § 146b.101 (b) of this chapter.

(b) The fee for the services rendered with respect to each immediate container in the sample of streptomycin or dihydrostreptomycin submitted in accordance with the requirements prescribed by this section shall be $10.00.

(c) Exemption of penicillin-streptomycin tablets and penicillin-dihydrostreptomycin tablets for veterinary use from certification: Penicillin-streptomycin tablets and penicillin-dihydrostreptomycin tablets that conform to the requirements of paragraph (a) of this section (except that they may contain one or more essential vitamin and mineral substances for nutritive purposes) shall be exempt from the requirements of sections 502 (l) and 507 of the act, if they comply with all the following conditions:

(1) They are intended solely for veterinary use and are conspicuously so labeled.

(2) If they contain added vitamins or minerals, the labels bear the name and quantity of each such substance and a statement that such substances are present only for furnishing additional vitamins and minerals while animals are eating less feed.

(3) The labels bear an expiration date that is not more than 18 months after the month during which the batch was last assayed and released by the manufacturer.

(4) The labels bear a statement that solutions prepared with the drugs are stable for not more than 24 hours.

(5) The circular or other labeling within or attached to the package bears information that only the antibiotics are intended for the prevention or treatment of the following conditions, and further, bears directions and warnings adequate for such use:

(i) Chronic respiratory disease (air-sac infection) in chickens.

(ii) Blue comb (mud fever, nonspecific infectious enteritis) in poultry.

§ 146a.89 *Procaine penicillin-streptomycin-neomycin in oil; procaine penicillin-dihydrostreptomycin-neomycin in oil; procaine penicillin-streptomycin-neomycin ointment; procaine penicillin-dihydrostreptomycin-neomycin ointment.* Procaine penicillin-streptomycin-neomycin in oil or procaine penicillin-dihydrostreptomycin-neomycin in oil conforms to all requirements and is subject to all procedures prescribed by § 146a.57 for procaine penicillin and streptomycin in oil and procaine penicillin and dihydrostreptomycin in oil. Procaine penicillin-streptomycin-neomycin ointment or procaine penicillin-dihydrostreptomycin-neomycin ointment conforms to all requirements and is subject to all procedures prescribed by § 146a.54 for procaine penicillin-streptomycin ointment and procaine penicillin-dihydrostreptomycin ointment, except that:

(a) It contains not less than 2.0 milligrams of neomycin per milliliter. The neomycin used conforms to the requirements prescribed for neomycin by § 146e.410 (a) (2) of this chapter.

(b) Each package shall bear on the outside wrapper or container and the immediate container the number of milligrams of neomycin in each milliliter of the batch, and its expiration date shall be 12 months after the month during which the batch was certified, except that the expiration date shall be 18 months or 24 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug as prepared by him is stable for such period of time: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(c) In addition to complying with the requirements of § 146a.54 (c) or § 146a.57 (a) (4), a person who requests certification of a batch shall submit with his request a statement showing the number of milligrams of neomycin in each milliliter or gram of the batch, the batch mark, and (unless it was previously submitted) the results and the date of the latest tests and assays of the neomycin used in making the batch for potency, toxicity, moisture, and pH. He shall also submit in connection with his request a sample consisting of not less than 7 immediate containers of the batch and (unless it was previously submitted) a sample consisting of 5 packages containing approximately equal portions of not less than 0.5 gram each of the neomycin used in making such batch.

(d) The fee for the services rendered with respect to each immediate container in the sample of neomycin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146a.90 *Procaine penicillin and benzathine penicillin G in streptomycin sulfate solution; procaine penicillin and benzathine penicillin G in dihydrostreptomycin sulfate solution (procaine penicillin and benzathine penicillin G in crystalline dihydrostreptomycin sulfate solution).* Procaine penicillin and benzathine penicillin G in streptomycin sulfate solution and procaine penicillin and benzathine penicillin G in dihydrostreptomycin sulfate solution conform to all requirements and are subject to all procedures prescribed by § 146a.67 for procaine penicillin in streptomycin sulfate solution and procaine penicillin in dihydrostreptomycin sulfate solution except that:

(a) Each milliliter shall contain not less than 100,000 units of procaine penicillin, not less than 100,000 units of benzathine penicillin G, and not less than 0.25 gram of streptomycin sulfate or dihydrostreptomycin sulfate, but each immediate container shall contain not less than 200,000 units of procaine penicillin, not less than 200,000 units of benzathine penicillin G, and not less than 0.5 gram of streptomycin sulfate or dihydrostreptomycin sulfate. The benzathine penicillin G used conforms to the requirements prescribed by § 146a.68 (a).

(b) In lieu of the directions prescribed by § 146a.67 (c) (1) (ii), each package shall bear on the outside wrapper or container and the immediate container the number of units of procaine penicillin, the number of units of benzathine penicillin G, and the number of grams of streptomycin sulfate or dihydrostreptomycin sulfate in each milliliter of the batch.

(c) In addition to complying with the requirements of § 146a.67 (d), a person who requests certification of a batch shall submit with his request a statement showing the batch mark, and (unless it was previously submitted) the results and the date of the latest tests and assays of the benzathine penicillin G used in making the batch for potency, crystallinity, and penicillin G content, and the number of units of benzathine penicillin G in each milliliter of the batch. He shall also submit in connection with his request a sample consisting of 3 packages containing approximately equal portions of not less than 0.5 gram each of the benzathine penicillin G used in making the batch.

(d) The fee for the services rendered with respect to each immediate container in the sample of benzathine penicillin G submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146a.91 *Benzathine penicillin G and streptomycin; benzathine penicillin G and dihydrostreptomycin.* Benzathine penicillin G and streptomycin and benzathine penicillin G and dihydrostreptomycin conform to all requirements prescribed by § 146a.77 for the dry mixture of benzathine penicillin G for aqueous injection and are subject to all procedures prescribed by that section for benzathine penicillin G for aqueous injection except that:

(a) It contains not less than 0.5 gram of streptomycin or dihydrostreptomycin for each 100,000 units of benzathine penicillin G.

(b) In lieu of the directions for labeling prescribed by § 146a.77 (c) (1) (ii), each package shall bear on the outside wrapper or container and the immediate container the number of units of penicillin and the number of grams of streptomycin or dihydrostreptomycin in the immediate container.

(c) In addition to complying with the requirements of § 146a.77 (d), a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the streptomycin or dihydrostreptomycin used in making the batch for potency, histamine content, streptomycin content if it is dihydrostreptomycin and crystallinity if it is crystalline dihydrostreptomycin, the number of units of benzathine penicillin G, and the number of grams of streptomycin or dihydrostreptomycin in each immediate container of the batch. He shall also submit in connection with his request a sample consisting of not less than 12 immediate containers of the batch and a sample of the streptomycin or dihydrostreptomycin used in making the batch consisting of 3 packages containing approximately equal portions of not less than 0.5 gram each, packaged in accordance with the requirements of § 146b.101 (b) of this chapter.

(d) The fee for the services rendered with respect to each immediate container in the sample of streptomycin or dihydrostreptomycin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146a.92 *Tablets benzathine penicillin G and crystalline penicillin.* Tablets benzathine penicillin G and crystalline penicillin conform to all requirements prescribed therefor by § 146a.27 for penicillin tablets and are subject to all procedures prescribed by that section for penicillin tablets, except that;

(a) Each tablet contains not less than 100,000 units of benzathine penicillin G and not less than 100,000 units of crystalline penicillin sodium or potassium penicillin.

(b) Their moisture content is not more than 4 percent.

(c) In lieu of the directions for labeling prescribed for penicillin tablets by § 146a.27 (c) (1) (ii), each package shall bear on the outside wrapper or container and the immediate container the number of units of each salt of penicillin.

(d) A person who requests certification of a batch shall submit in connection with his request an accurately representative sample of the batch, consisting of not less than 30 tablets.

§ 146a.93 *Penicillin-streptomycin powder; penicillin-dihydrostreptomycin powder.* Penicillin-streptomycin powder and penicillin-dihydrostreptomycin powder conform to all the requirements and are subject to all procedures prescribed by § 146a.88 for penicillin-streptomycin tablets and penicillin-dihydrostreptomycin tablets, except that:

(a) Each gram contains not less than 50,000 units of penicillin and not less than 5 milligrams of streptomycin or dihydrostreptomycin.

(b) In lieu of the labeling prescribed by § 146a.88 (a) (2), each package shall bear on the outside wrapper or container and the immediate container the number of units of penicillin and the number of milligrams of streptomycin or dihydrostreptomycin in each gram and the statement "Expiration date -------," the blank being filled in with the date which is 12 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(c) In lieu of the minimum number of tablets prescribed by § 146a.88 (a) (3), a person who requests certification of a batch shall submit with his request a sample of the batch consisting of 1 immediate container for each 5,000 immediate containers but in no case less than 6 or more than 12 immediate containers. Such sample shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(d) The fee for the services rendered with respect to each immediate container in the sample submitted in accordance with the requirements prescribed by paragraph (c) of this section shall be $4.00.

(e) Exemption of penicillin-streptomycin powder and penicillin-dihydrostreptomycin powder for veterinary use from certification: Penicillin-streptomycin powder and penicillin-dihydrostreptomycin powder that conform to the requirements of this section (except that they may contain one or more essential vitamin and mineral substances for nutritive purposes) shall be exempt from the requirements of section 502 (l) and 507 of the act, if they comply with all the following conditions:

(1) They are intended solely for veterinary use and are conspicuously so labeled.

(2) If they contain added vitamins or minerals, the labels bear the name and quantity of each such substance and a statement that such substances are present only for furnishing additional vitamins and minerals while animals are eating less feed.

(3) The labels bear an expiration date that is not more than 12 months after the month during which the batch was last assayed and released by the manufacturer.

(4) The labels bear a statement that solutions prepared with the drugs are stable for not more than 24 hours.

(5) The circular or other labeling within or attached to the package bears information that only the antibiotics are intended for the prevention or treatment of the following conditions, and further, bears directions and warnings adequate for such use:

(i) Bacterial enteritis in swine.

(ii) Bacterial calf scours.

(iii) Chronic respiratory disease (air-sac infection) in chickens.

(iv) Blue comb (mud fever, nonspecific infectious enteritis) in poultry.

(v) Infectious sinusitis in poultry.

§ 146a.94 *Dibenzylamine penicillin G (dibenzylamine penicillin G salt)*—(a) *Standards of identity, strength, quality, and purity.* Dibenzylamine penicillin G is the crystalline dibenzylamine salt of penicillin G. It contains not less than 85 percent by weight of the dibenzylamine salt of penicillin G. Each such drug is so purified and dried that:

(1) Its potency is not less than 975 units per milligram.

(2) It is sterile.

(3) It is nontoxic.

(4) It is nonpyrogenic.

(5) Its moisture content is not more than 4.0 percent.

(6) Its pH in saturated aqueous solution is not less than 5.0 and not more than 7.5.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its outside wrapper or container and the immediate container, as hereinafter indicated, the following:

(1) The batch mark.

(2) The weight of the drug and the number of units in the immediate container.

(3) The statement "Expiration date ----------," the blank being filled in with the date which is 18 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(4) The statement "For manufacturing use only."

(5) The statement "Caution: Federal law prohibits dispensing without prescription."

(d) *Request for certification, check tests and assays; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the weight of the drug and the number of units in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising such batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, sterility, toxicity, pyrogens, moisture, pH, crystallinity, and the penicillin G content.

(2) Such person shall submit with his request an accurately representative sample of the batch, consisting of the following:

(i) For all tests except sterility; 10 packages.

(ii) For sterility test; 10 packages.

Each such package shall contain approximately 300 milligrams taken from different parts of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(3) In connection with contemplated requests for certification of batches of another drug in the manufacture of which dibenzylamine penicillin G is to be used, the manufacturer of a batch that is to be so used may request the Commissioner to make check tests and assays on a sample of such batch, taken as prescribed by subparagraph (2) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (2) (i) and (3) of this section.

(2) If the Commissioner considers that investigations other than the examination of such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.95 *Dibenzylamine penicillin and potassium penicillin powder, buffered*—(a) *Standards of identity, strength, quality, and purity.* Dibenzylamine penicillin and potassium penicillin powder, buffered, is a dry mixture of dibenzylamine penicillin G and potassium penicillin G, with or without one or more suitable sulfonamides, and with one or more suitable and harmless buffer substances, colorings, and flavorings. It shall contain not less than 100,000 units of potassium pencillin G for each 200,000 units of dibenzylamine penicillin G. Its moisture content is not more than 1 percent. Its pH is not less than 5.5 and not more than 7.5. The dibenzylamine penicillin G used conforms to the requirements of § 146a.94 (a), except subparagraphs (2) and (4) of that paragraph. The potassium penicillin used conforms to the requirements of § 146a.24 (a) for potassium penicillin, except subparagraphs (2) and (4) of that paragraph. Each other ingredient used, if its name is recognized in the U. S. P. or N. F. conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of units of dibenzylamine penicillin and the number of units of potassium penicillin in the immediate container.

(iii) If it contains sulfonamides, the name and quantity of each in the immediate container.

(iv) The name of each buffer substance used in making the batch.

(v) The statement "Expiration date ________," the blank being filled in with the date which is 12 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(vi) The statement "Warning—Not for injection."

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the label and labeling, if it contains sulfonamides, after the name "dibenzylamine penicillin and potassium penicillin powder, buffered," wherever it appears, the words "with sulfonamides," in juxtaposition with such name.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless they were previously submitted) the dates on which the latest assays of the dibenzylamine penicillin G and the potassium penicillin G used in making the batch were completed, the number of units of dibenzylamine penicillin G and the number of units of potassium penicillin G in each container of the batch, the date on which the latest assay comprising such batch was completed, the quantity of each ingredient used in making the batch, and a statement that each such ingredient conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency and moisture.

(ii) The dibenzylamine penicillin G used in making the batch; potency, toxicity, moisture, pH, crystallinity, and penicillin G content.

(iii) The potassium penicillin G used in making the batch; potency, toxicity, moisture, pH, penicillin G content, crystallinity, and heat stability.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 6 or more than 12 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The dibenzylamine penicillin G used in making the batch; 3 packages, each containing approximately equal portions of not less than 500 milligrams packaged in accordance with the requirements of § 146a.94 (b).

(iii) The potassium penicillin G used in making the batch; 3 packages, each containing approximately equal portions of not less than 250 milligrams packaged in accordance with the requirements of § 146a.24 (b).

(iv) In case of an initial request for certification, each other ingredient used in making the batch; 1 package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) and (iii) of this paragraph, and no sample referred to in subparagraph (3) (ii) and (iii) of this

paragraph, is required if such results or samples have been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i), (ii), (iii), and (iv) of this section.

(2) If the Commissioner considers that investigations other than the examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.96 *Dibenzylamine penicillin and streptomycin in oil; dibenzylamine penicillin and dihydrostreptomycin in oil.* Dibenzylamine penicillin and streptomycin in oil and dibenzylamine penicillin and dihydrostreptomycin in oil conform to all the requirements prescribed by § 146a.57 for procaine penicillin and streptomycin in oil and procaine penicillin and dihydrostreptomycin in oil and are subject to all procedures prescribed by § 146a.57 for procaine penicillin and streptomycin in oil and procaine penicillin and dihydrostreptomycin in oil, except that dibenzylamine penicillin is used in lieu of procaine penicillin. The dibenzylamine penicillin used conforms to the requirements of § 146a.94 (a), except subparagraphs (2) and (4) of that paragraph.

§ 146a.97 *Hydrabamine penicillin G (hydrabamine penicillin G salt)*—(a) *Standards of identity, strength, quality, and purity.* Hydrabamine penicillin G is the crystalline salt N,N'-bis-(dehydroabietyl) ethylenediamine dipenicillin G. It contains not less than 85 percent by weight of the hydrabamine salt of penicillin G. It is so purified and dried that:

(1) Its potency is not less than 845 units per milligram.

(2) It is nontoxic.

(3) Its moisture content is not more than 2 percent.

(4) Its pH in a saturated aqueous solution is not less than 4.0 and not more than 7.5.

(5) Its extinction coefficient $E^{1\%}_{1\,\text{cm.}}$ is not less than 8 at 276 millimicrons.

(b) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its outside wrapper or container and the immediate container, as hereinafter indicated, the following:

(1) The batch mark.

(2) The number of units per milligram and the number of grams in the immediate container.

(3) The statement "Expiration date ______," the blank being filled in with the date that is 24 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(4) The statement "For use in the manufacture of nonparenteral drugs only."

(5) The statement "Caution: Federal law prohibits dispensing without prescription."

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, and the date on which the latest assay of the drug comprising such batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, toxicity, moisture, pH, crystallinity, the penicillin G content, and extinction coefficient.

(2) Such person shall submit with his request an accurately representative sample of the batch, consisting of 10 packages, each containing approximately 300 milligrams taken from a different part of such batch, packaged in accordance with the requirements of paragraph (b) of this section.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) (2) of this section.

(2) If the Commissioner considers that investigations other than examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.98 *Hydrabamine penicillin G oral suspension*—(a) *Standards of identity, strength, quality, and purity.* Hydrabamine penicillin G oral suspension is hydrabamine penicillin G and one or more suitable and harmless suspending or dispersing agents, buffer substances, and preservatives, with or without one or more suitable and harmless colorings and flavorings. Its potency is not less than 60,000 units per milliliter. Its pH is not less than 5.5 and not more than 7.0. The hydrabamine penicillin G used conforms to the requirements of § 146a.97 (a). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* The immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of units in each milliliter of the batch.

(iii) The name of each buffer substance and the name and quantity of each preservative used in making the batch.

(iv) The statement "Shake well."

(v) The statement "Expiration date ______," the blank being filled in with the date that is 12 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container.

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the hydrabamine penicillin G used in making such batch was completed, the potency per milliliter of the batch, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch, and a statement that each such ingredient conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch: average potency per milliliter, pH.

(ii) The hydrabamine penicillin G used in making the batch: potency, toxicity, moisture, pH, crystallinity, the penicillin G content, and the extinction coefficient.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch: 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 or more than 12 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The hydrabamine penicillin G used in making the batch: 10 packages, each containing equal portions of not less than 300 milligrams, packaged in accordance with the requirements of § 146a.97 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i), (ii), and (iii) of this section.

(2) If the Commissioner considers that investigations, other than examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.99 *Capsules crystalline penicillin G (capsules crystalline penicillin G potassium, capsules crystalline penicillin G sodium)*—(a) *Standards of identity, strength, quality, and purity.* Capsules crystalline penicillin are crystalline penicillin G, sodium or potassium, with or without one or more suitable and harmless buffer substances, vitamin substances, and vegetable oils, enclosed in suitable and harmless gelatin capsules. The potency of each capsule is not less than 50,000 units and its moisture content is not more than 1.5 percent. The crystalline penicillin G used conforms to the requirements of § 146a.24 (a), except § 146a.24 (a) (2) and (4). Each other ingredient used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging; labeling; request for certification, samples; fees.* Capsules crystalline penicillin G conform to all requirements and procedures prescribed for crystalline penicillin G tablets by § 146a.27 (b), (c), (d), and (e), except that:

(1) If it is for use in the preparation of oral solutions, each package shall bear on its outside wrapper or container and the immediate container a statement that contains adequate directions for preparing such solutions and a statement that such solutions should be used immediately.

(2) If it contains vitamin substances, each package shall bear on the outside wrapper or container and the immediate container the name and quantity of each such ingredient.

(3) It shall be labeled with an expiration date that is 36 months, except that if it contains one or more vitamin substances it shall be labeled with an expiration date that is 12 months, after the month during which the batch was certified, except that the blank may be filled in with the date that is 18 months or 24 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed for the drug.

(4) If it contains one or more vitamin substances, after the name "capsules crystalline penicillin G potassium," or "capsules crystalline penicillin G sodium," wherever either such name appears, the words "with vitamin ______" (the blank being filled in with the name of the vitamin ingredient used) or "with vitamins" (if it contains more than one vitamin ingredient), in juxtaposition with such name.

§ 146a.100 *Benzathine penicillin G in oil.* Benzathine penicillin G in oil conforms to all requirements and is subject to all procedures prescribed by § 146a.45 for sterile procaine penicillin in oil, except that:

(a) Benzathine penicillin G is used in lieu of procaine penicillin. The benzathine penicillin used conforms to the requirements of § 146a.68 (a).

(b) Its moisture content is not more than 4 percent.

§ 146a.101 *Benzathine penicillin G and procaine penicillin G in oil.* (a) Benzathine penicillin G and procaine penicillin G in oil conforms to all requirements and is subject to all procedures prescribed by § 146a.45 for sterile procaine penicillin in oil, except that:

(1) Each milliliter contains not less than 150,000 units each of benzathine penicillin G and procaine penicillin G, unless it is intended solely for veterinary use and is conspicuously so labeled. The benzathine penicillin G used conforms to the requirements of § 146a.68 (a).

(2) Its moisture content is not more than 4.0 percent.

(3) In lieu of the directions for labeling prescribed for procaine penicillin in oil by § 146a.45 (c) (1) (ii), each package shall bear on the outside wrapper or container and the immediate container the number of units of benzathine penicillin G and the number of units of procaine penicillin G in each milliliter of the batch.

(4) In addition to complying with the requirements of § 146a.45 (d), a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the benzathine penicillin G used in making the batch for potency, sterility, pyrogens, toxicity, moisture, pH, crystallinity, and penicillin G content, and the number of units each of benzathine penicillin G and procaine penicillin in each milliliter of the batch. He shall also submit in connection with his request a sample consisting of not less than 4 packages of the batch and (unless it was previously submitted) a sample of the benzathine penicillin G used in making the batch, consisting of 20 packages, each containing approximately equal portions of not less than 300 milligrams.

(b) The fee for the services rendered with respect to each package of benzathine penicillin G submitted in accordance with the requirements prescribed therefor by this section shall be $2.00.

§ 146a.102 *Benzathine penicillin G-procaine penicillin G-streptomycin in oil; benzathine penicillin G-procaine penicillin G-dihydrostreptomycin in oil.* (a) Benzathine penicillin G-procaine penicillin G-streptomycin in oil and benzathine penicillin G-procaine penicillin G-dihydrostreptomycin in oil conform to all requirements and are subject to all procedures prescribed by § 146a.101 for benzathine penicillin G and procaine penicillin G in oil, except that:

(1) Each milliliter shall contain not less than 250 milligrams of streptomycin or dihydrostreptomycin. The streptomycin used conforms to the standards prescribed by § 146b.101 (a) of this chapter. The dihydrostreptomycin used conforms to the standards prescribed by § 146b.103 of this chapter.

(2) In lieu of the directions for labeling prescribed for benzathine penicillin G and procaine penicillin G in oil by § 146a.101 (a) (3), each package shall bear on the outside wrapper or container and the immediate container the number of units of benzathine penicillin G, the number of units of procaine penicil-

lin G, and the number of milligrams of streptomycin or dihydrostreptomycin in each milliliter of the batch.

(3) In addition to complying with the requirements of § 146a.101 (a) (4), a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the streptomycin or dihydrostreptomycin used in making the batch for potency, sterility, toxicity, pyrogens, histamine, moisture, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin; and the number of units of benzathine penicillin G and procaine penicillin, and the number of milligrams of streptomycin or dihydrostreptomycin in each milliliter of the batch. He shall also submit in connection with his request a sample consisting of not less than 5 immediate containers of the batch and (unless it was previously submitted) a sample consisting of 5 packages (for all tests except sterility) and 10 packages (for sterility testing), each containing approximately 0.5 gram of the streptomycin or dihydrostreptomycin used in making the batch, packaged in accordance with the requirements of § 146b.101 (b) of this chapter.

(b) The fee for the services rendered with respect to each immediate container in the sample of streptomycin or dihydrostreptomycin submitted, for all tests except sterility, in accordance with the requirements prescribed by this section, shall be $10.00.

§ 146a.103 *Penicillin V (phenoxymethyl penicillin)*—(a) *Standards of identity, strength, quality, and purity.* Penicillin V is crystalline phenoxymethyl penicillin. It contains not less than 90 percent of penicillin V. It is so purified and dried that:

(1) Its potency is not less than 1,500 units per milligram.

(2) It is nontoxic.

(3) Its moisture content is not more than 2.0 percent.

(4) Its pH in a saturated aqueous solution is not less than 2.5 and not more than 4.0.

(b) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its outside wrapper or container and the immediate container, as hereinafter indicated, the following:

(1) The batch mark.

(2) The number of units per milligram and the number of grams in the immediate container.

(3) The statement "Expiration date ---------------," the blank being filled in with the date that is 24 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(4) The statement "For use in the manufacture of nonparenteral drugs only."

(5) The statement "Caution: Federal law prohibits dispensing without prescription."

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, and the date on which the latest assay of the drug comprising such batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, toxicity, moisture, pH, crystallinity, and penicillin V content.

(2) Such person shall submit with his request an accurately representative sample of the batch, consisting of 10 packages, each containing approximately 300 milligrams taken from a different part of such batch, packaged in accordance with the requirements of paragraph (b) of this section.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) (2) of this section.

(2) If the Commissioner considers that investigations other than examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146a.106 *Tablets benzathine penicillin G and penicillin V.* (a) Tablets benzathine penicillin G and penicillin V conform to all requirements and are subject to all procedures prescribed by § 146a.27 for tablets benzathine penicillin G, except that each tablet contains not less than 50,000 units of penicillin V.

(b) In lieu of the labeling directions prescribed for tablets benzathine penicillin G by § 146a.27 (c) (1) (ii), each package shall bear on the outside wrapper or container and the immediate container the number of units of each kind of penicillin.

(c) In addition to complying with the requirements of § 146a.27 (d), a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless they were previously submitted) the results and the date of the latest tests and assays of the penicillin V used in making the batch for potency, toxicity, moisture, pH, crystallinity, and penicillin V content. He shall also submit in connection with his request a sample consisting of not less than 30 tablets of the batch and (unless it was previously submitted) a sample consisting of 10 packages containing approximately equal portions of not less than 300 milligrams each of the penicillin V used in making the batch, packaged in accordance with the requirements of § 146a.103 (b).

(d) The fee for the services rendered with respect to each immediate container in the sample of penicillin V submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146a.107 *Capsules penicillin V.* Capsules penicillin V are capsules that conform to all requirements and are subject to all procedures prescribed by § 146a.27 for tablets penicillin V, except that the moisture content of such capsules is not more than 2 percent.

§ 146a.108 *Procaine penicillin-streptomycin-polymyxin in oil; procaine penicillin-dihydrostreptomycin - polymyxin in oil.* Procaine penicillin-streptomycin-polymyxin in oil and procaine penicillin-dihydrostreptomycin - polymyxin in oil conform to all requirements and are subject to all procedures prescribed by § 146a.57 for procaine penicillin and streptomycin in oil and procaine penicillin and dihydrostreptomycin in oil, except that:

(a) They contain not less than 50,000 units of polymyxin B per single-dose container. The polymyxin B used conforms to the requirements prescribed for polymyxin B by § 146b.107 (a) of this chapter.

(b) In lieu of the labeling prescribed by § 146a.57 (a) (3), each package shall bear on the outside wrapper or container and the immediate container the number of units of penicillin, the number of milligrams of streptomycin or dihydrostreptomycin, and the number of units of polymyxin B per milliliter or per prescribed dose; if it contains one or more of the active ingredients specified in § 146a.57 (a) (2), the name and quantity of each; the statement "For udder instillation of cattle only" and the statement "Expiration date ----," the blank being filled in with the date that is 12 months after the month during which the batch was certified. Each package shall also bear on its label and labeling, if it contains one or more of the active ingredients specified in § 146a.57 (a) (2), after the name "procaine penicillin - streptomycin - polymyxin in oil" or "procaine penicillin-dihydrostreptomycin-polymyxin in oil," wherever it appears, the words "with ------------------- (the blank being filled in with the common or usual name of each such ingredient)," in juxtaposition with such name.

(c) In addition to complying with the requirements of § 146a.57 (a) (4), a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and date of the latest tests and assays of the polymyxin used in making the batch for potency and toxicity. He shall also submit in connection with his request a sample consisting of not less than 6 immediate containers of the batch and (unless it was previously submitted) a sample consisting of 5 packages containing equal portions of not less than 0.5 gram each of the polymyxin used in making the batch.

(d) The fee for the services rendered with respect to each immediate container in the sample of polymyxin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

Part 146b—Certification of Streptomycin (or Dihydrostreptomycin) and Streptomycin- (or Dihydrostreptomycin-) Containing Drugs

Sec.
146b.101 Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride.
146b.102 Streptomycin ointment; dihydrostreptomycin ointment.
146b.103 Dihydrostreptomycin sulfate, crystalline dihydrostreptomycin sulfate, dihydrostreptomycin hydrochloride.
146b.104 Streptomycin tablets; dihydrostreptomycin tablets.
146b.105 Streptomycin for topical use; streptomycin with --------- for topical use.
146b.106 Streptomycin sulfate solution; dihydrostreptomycin sulfate solution.
146b.107 Streptomycin - polymyxin - bacitracin tablets.
146b.108 Streptomycin syrup, streptomycin and kaolin in gel; dihydrostreptomycin syrup, dihydrostreptomycin and kaolin in gel.
146b.109 Streptomycin - bacitracin - polymyxin gauze pads.
146b.110 Streptomycin otic with antifungal agent, streptomycin otic with -----; dihydrostreptomycin otic with antifungal agent, dihydrostreptomycin otic with --------.
146b.111 Streptomycin - kaolin - pectin - aluminum hydroxide gel powder veterinary; dihydrostreptomycin-kaolin-pectin-aluminum hydroxide gel powder veterinary.
146b.112 Streptomycin for inhalation therapy; dihydrostreptomycin for inhalation therapy.
146b.113 Dihydrostreptomycin - streptomycin sulfates.
146b.114 Streptomycin sulfate oral veterinary.
146b.115 Streptomycin sulfate powder oral veterinary; streptomycin sulfate granules oral veterinary.
146b.116 Streptomycylidene isonicotinyl hydrazine sulfate.
146b.117 Dihydrostreptomycin - streptomycin sulfates solution.
146b.118 Streptomycin - penicillin - sulfonamide with kaolin and pectin; dihydrostreptomycin - penicillin-sulfonamide with kaolin and pectin.
146b.119 Streptomycin hydrochloride solution oral veterinary; streptomycin sulfate solution oral veterinary.
146b.120 Dihydrostreptomycin - streptomycin sulfates with isonicotinic acid hydrozide.
146b.121 Streptomycin-erythromycin ointment.
146b.122 Streptomycin - chlortetracycline-chloramphenicol-bacitracin dental cement; dihydrostreptomycin - chlortetracycline - chloramphenicol - bacitracin dental cement.
Sec.
146b.123 Streptomycin - sodium sulfathiazole solution veterinary; dihydrostreptomycin - sodium sulfathiazole solution veterinary.
146b.124 Streptomycin - polymyxin - neomycin ointment; dihydrostreptomycin-polymyxin-neomycin ointment.

Authority: §§ 146b.101 to 146b.124 issued under sec. 701, 52 Stat. 1055; 21 U. S. C. 371. Interpret or apply sec. 507, 59 Stat. 463, as amended; 21 U. S. C. 357.

§ 146b.101 *Streptomycin sulfate, streptomycin hydrochloride, streptomycin phosphate, streptomycin trihydrochloride calcium chloride (streptomycin calcium chloride complex)*—(a) *Standards of identity, strength, quality, and purity.* Streptomycin sulfate is the sulfate salt of a kind of streptomycin or a mixture of two or more such salts; streptomycin hydrochloride is the hydrochloride salt of a kind of streptomycin or a mixture of two or more such salts; streptomycin phosphate is the phosphate salt of a kind of streptomycin or a mixture of two or more such salts; streptomycin trihydrochloride calcium chloride is the double salt of a kind of streptomycin or a mixture of two or more such salts. Each such drug is so purified and dried that:

(1) Its potency is not less than 650 micrograms per milligram;

(2) It is sterile;

(3) It is nontoxic;

(4) It is nonpyrogenic;

(5) It contains no histamine or histamine-like substances;

(6) Its moisture content is not more than 5.0 percent;

(7) Its pH in aqueous solution of 0.2 gram per millimeter is not less than 4.5 and not more than 7.0.

(b) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing, it shall be in immediate containers of colorless (unless it is intended solely for veterinary use) transparent glass closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness. Unless it is intended solely for veterinary use and is conspicuously so labeled, each such container shall contain 0.5 gram, 1.0 gram, 2.0 grams, 3.0 grams, 4.0 grams, 5.0 grams, or 10.0 grams, and each may be packaged in combination with a container of the solvent water for injection U. S. P., dextrose injection 5 percent U. S. P. or physiological salt solution U. S. P.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container

(i) The batch mark;

(ii) The number of grams in the immediate container;

(iii) The statement "Expiration date --------," the blank being filled in with the date which is 48 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) The statement "For Manufacturing Use," "For Repacking," or "For Manufacturing Use or Repacking" when packaged for repacking or for use as an ingredient in the manufacture of another drug, as the case may be.

(2) On the outside wrapper or container, the statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing:

(i) If it is intended for use by man, adequate directions and warnings for its use by practitioners licensed by law to administer such drug.

(ii) If it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(iii) The conditions under which such solutions should be stored, including the statement "Sterile solutions may be stored at room temperature for 4 weeks without significant loss of potency.

(d) *Request for certification, check tests and assays; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of grams in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, sterility, toxicity, pyrogens, histamine content, moisture, and pH. If such batch or any part thereof is to be packaged with a solvent such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) If such batch is packaged for dispensing, such person shall submit with his request an accurately representative sample of the batch, consisting of the following:

(i) For all tests except sterility; one immediate container for each 5,000 immediate containers in such batch, but in no case less than 5 or more than 12 immediate containers.

(ii) For sterility testing; 10 immediate containers.

Such sample shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(3) If such batch is packaged for repacking or for use as an ingredient in the manufacture of another drug, such person shall submit with his request an accurately representative sample of the batch, consisting of the following:

(i) For all tests except sterility; 5 packages.

(ii) For sterility testing; 10 packages.

Each such package shall contain approximately 0.5 gram taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(4) In connection with contemplated requests for certification of repackaged batches or batches of another drug in the manufacture of which it is to be used, the manufacturer of a batch which is to be so repacked or used may request the Commissioner to make check tests and assays on a sample of such batch taken as prescribed by subparagraph (3) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $10.00 for each immediate container in the samples submitted in accordance with paragraph (d) (2) (i), (3) (i), and (4) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146b.102 *Streptomycin ointment; dihydrostreptomycin ointment*—(a) *Standards of identity, strength, quality, and purity.* Streptomycin ointment and dihydrostreptomycin ointment is streptomycin or dihydrostreptomycin in a suitable and harmless ointment base, with or without suitable and harmless dispersing and suspending agents and preservatives. Its potency is not less than 5,000 micrograms per gram of ointment. The streptomycin used conforms to the requirements of § 146b.101 (a), except subparagraphs (2), (4), (5), and (6) of that paragraph. The dihydrostreptomycin used conforms to the requirements of § 146b.103, except the standards for sterility, pyrogens, histamine, and moisture. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Streptomycin ointment and dihydrostreptomycin ointment shall be packaged in collapsible tubes which shall be well-closed containers as defined by the U. S. P., and each such tube shall not be larger than the 2-ounce size, except if it is labeled solely for hospital use it may be packaged in immediate containers of glass which meet the test for tight containers as defined by the U. S. P. The composition of the immediate container and closure shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of streptomycin ointment shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of micrograms per gram of the batch;

(iii) If the batch contains preservatives, the name and quantity of each such substance used; and

(iv) The statement "Expiration date ----------------," the blank being filled in with the date which is 24 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of streptomycin ointment or dihydrostreptomycin ointment shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the streptomycin used in making such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that each component of the ointment base used conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency.

(ii) The streptomycin or dihydrostreptomycin used in making the batch; potency, toxicity, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin sulfate.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers or more than 12 immediate containers unless each such container is packaged for hospital use and contains more than 2 ounces, in which case the sample shall consist of approximately 1 ounce of ointment for each 5,000 immediate containers in the batch, but in no case less than five 1-ounce portions or more than twelve 1-ounce portions. Such sample shall be collected by taking single immediate containers or 1-ounce portions at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The streptomycin or dihydrostreptomycin used in making the batch; 5 packages containing approximately equal portions of not less than 0.5 gram each, packaged in accordance with the requirements of § 146b.101 (b).

(iii) In case of an initial request for certification, the ingredients used in making the ointment base of the batch; one package of each containing approximately 200 grams, except for the suspending and dispersing agents used, in which case the sample shall consist of approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of streptomycin ointment or dihydrostreptomycin ointment under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i), (ii), and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification, unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146b.103 *Dihydrostreptomycin sulfate, crystalline dihydrostreptomycin sulfate, dihydrostreptomycin hydrochloride.* (a) Dihydrostreptomycin sulfate is the hydrogenated sulfate salt of a kind of streptomycin or a mixture of two or more such salts; crystalline dihydrostreptomycin sulfate is the hydrogenated crystalline sulfate salt of a kind of streptomycin or a mixture of two or more such salts: dihydrostreptomycin hydrochloride is the hydrogenated hydrochloride salt of a kind of streptomycin or a mixture of two or more such salts. Each such drug conforms to all requirements prescribed by § 146b.101 for streptomycin sulfate and streptomycin hydrochloride, and is subject to all procedures prescribed by § 146b.101 for streptomycin sulfate and streptomycin hydrochloride, except that:

(1) Its potency is not less than 650 micrograms per milligram, except that if it is crystalline dihydrostreptomycin sulfate its potency is not less than 725 micrograms per milligram.

(2) Its content of streptomycin sulfate or streptomycin hydrochloride is not more than 3.0 percent when calculated as streptomycin base, except that if it is crystalline dhyidrostreptomycin sulfate its content of streptomycin sulfate is not more than 1.0 percent.

§ 146b.104 *Streptomycin tablets; dihydrostreptomycin tablets*—(a) *Standards of identity, strength, quality, and purity.* Streptomycin tablets and dihydrostreptomycin tablets is streptomycin or dihydrostreptomycin tableted with or without glucuronolactone, kaolin or other suitable and harmless absorbent ingredients, pectin, and dried aluminum hydroxide gel, and with or without the addition of one or more suitable and harmless diluents, binders, lubricants, colorings, and flavorings. If it is intended solely for veterinary use and is conspicuously so labeled, it may contain vitamin A, one or more suitable sulfonamides, or both. The potency of each tablet is not less than 50 milligrams. Its moisture content is not more than 5 percent. The streptomycin used conforms to the standards prescribed therefor by § 146b.101 (a), except subparagraphs (2) and (4) of that paragraph or in the case of tablets for veterinary use, streptomycin sulfate oral veterinary conforming to the standards in § 146b.114 (a) may be used. The dihydrostreptomycin used conforms to the standards prescribed therefor by § 146b.103, except the standards for sterility and pyrogens. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each streptomycin or dihydrostreptomycin tablet is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the tablets by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of streptomycin or dihydrostreptomycin tablets shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The potency of each tablet of the batch;

(iii) The statement "Expiration date _________," the blank being filled in with the date which is 24 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) If the batch contains, in addition to streptomycin or dihydrostreptomycin, one or more of the other active ingredients specified in paragraph (a) of this section, the name and quantity of each such other ingredient in each tablet.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the label and labeling, if it contains, in addition to streptomycin or dihydrostreptomycin, one or more of the other active ingredients specified in paragraph (a) of this section, after the name "Streptomycin Tablets" or "Dihydrostreptomycin Tablets," wherever it appears, the words "with ______________ (the blank being filled in with the common or usual name of each such other ingredient)", in juxtaposition with such name.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of streptomycin or dihydrostreptomycin tablets shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the streptomycin or dihydrostreptomycin used in making such batch was completed, the potency of each tablet, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per tablet and average moisture.

(ii) The streptomycin or dihydrostreptomycin used in making the batch; potency, toxicity, histamine content, moisture, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin sulfate.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one tablet for each 5,000 tablets in the batch, but in no case less than 20 tablets or more than 100 tablets, collected by taking single tablets at such intervals throughout the entire time of tableting that the quantities tableted during the intervals are approximately equal.

(ii) The streptomycin or dihydrostreptomycin used in making the batch; five packages containing approximately equal portions of not less than 0.5 gram each, packaged in accordance with the requirements of § 146b.101 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the service rendered with respect to each batch of streptomycin or dihydrostreptomycin tablets under the regulations in this part shall be:

(1) $1.00 for each tablet in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $10.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such tablets and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification, unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146b.105 *Streptomycin for topical use; streptomycin with ----- (the blank being filled in with the name of the vehicle if a package combination) for topical use*—(a) *Standards of identity, strength, quality, and purity.* Streptomycin for topical use conforms to all the requirements prescribed by § 146b.101 (a) for streptomycin, and may be packaged in combination with a container of a suitable and harmless vehicle.

(b) *Packaging.* The immediate container of streptomycin for topical use shall be of colorless transparent glass so closed as to be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that its contents cannot be used without destroying such seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each such container shall contain not less than 20 milligrams.

(c) *Labeling.* Each package of streptomycin for topical use shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams in the immediate container;

(iii) The statement "Expiration date --------------------," the blank being filled in with the date which is 48 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) The statement "Caution: Not for intravenous or systemic medication."

(2) If it is a package combination, on the immediate container of the vehicle in the combination:

(i) A statement giving the method of dissolving the streptomycin in the vehicle and the statement "The solution may be stored at room temperature for 1 week without significant loss of potency";

(ii) The potency per milliliter after the streptomycin has been dissolved therein; and

(iii) The statement "Caution: Not for intravenous or systemic medication."

(3) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of streptomycin for topical use shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the number of milligrams in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, sterility, toxicity, pyrogens, histamine content, moisture, and pH. If such batch, or any part thereof, is to be packaged with a vehicle, such request shall be accompanied by a statement that such vehicle conforms to the requirements prescribed therefor by this section.

(2) Such person shall submit in connection with his request an accurately representative sample of the batch, consisting of the following:

(i) For all tests except sterility; one immediate container for each 5,000 immediate containers in such batch, but in no case less than 50 or more than 100 immediate containers.

(ii) For sterility testing; 10 immediate containers.

Such samples shall be collected by taking single immediate containers, before or after labeling, at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(3) In case of an initial request for the certification of a batch of streptomycin for topical use which is to be packaged in combination with a container of a vehicle, or when any change is made in the composition of such vehicle, such person shall submit in connection with his request five packages of the vehicle included in the combination.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $1.00 for each immediate container in the sample submitted in accordance with paragraph (d) (2) (i) of this section; $4.00 for each package submitted with the samples in accordance with paragraph (d) (3) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification, unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146b.106 *Streptomycin sulfate solution; dihydrostreptomycin sulfate solution (crystalline dihydrostreptomycin sulfate solution)*—(a) *Standards of identity, strength, quality, and purity.* Streptomycin sulfate solution is an aqueous solution of streptomycin sulfate. Dihydrostreptomycin sulfate solution is an aqueous solution of dihydrostreptomycin sulfate or crystalline dihydrostreptomycin sulfate. Such solution conforms to all standards prescribed by § 146b.101 for streptomycin sulfate or § 146b.103 for dihydrostreptomycin sulfate or crystalline dihydrostreptomycin sulfate, except the limitation on moisture content, and except that:

(1) Its potency is not less than 250 milligrams per milliliter and not more than 500 milligrams per milliliter, unless it is intended solely for veterinary use and is conspicuously so labeled.

(2) It contains one or more suitable and harmless preservatives.

(3) Its pH is not less than 5.0 and not more than 8.0.

(4) It may contain one or more suitable and harmless buffer substances and stabilizing agents.

(b) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing it shall be in immediate containers of colorless (unless it is intended solely for veterinary use) transparent glass closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness, unless it is packaged to contain a single dose. Each such container shall contain not less than 1.0 milliliter and not more than 50 milliliters, unless it is intended solely for veterinary use and is conspicuously so labeled.

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams in each milliliter in the immediate container;

(iii) The statement "Expiration date ------------," the blank being filled in with the date which is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 18 months or 24 months or 36 months or 48 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such time period such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) The name and quantity of each preservative used; and

(v) The statement "For manufacturing use," "For repacking," or "For manufacturing use or repacking," when packaged for repacking or for use as an ingredient in the manufacture of another drug, as the case may be.

(2) On the outside wrapper or container:

(i) The statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)," unless the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section after having been stored at room temperature.

(ii) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing:

(i) If it is intended for use by man, adequate directions and warnings for its use by practitioners licensed by law to administer such drug.

(ii) If it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification, check tests and assays; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of milligrams or grams dissolved in each of such packages, the date on which the latest assay of the drug comprising such batch was completed, and if it is crystalline dihydrostreptomycin sulfate solution, the batch mark and (unless it was previously submitted) the date on which the latest assay of the crystalline dihydrostreptomycin sulfate used in making such batch was completed.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, toxicity, pyrogens, histamine content, pH, and streptomycin content, if it is dihydrostreptomycin sulfate or crystalline dihydrostreptomycin sulfate.

(ii) If crystalline dihydrostreptomycin sulfate is used in making the batch; potency and crystallinity.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch, if packaged for dispensing:

(*a*) For all tests except sterility; one immediate container for each 5,000 immediate containers in such batch, but in no case less than 5 or more than 12 immediate containers.

(*b*) For sterility testing; 10 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The batch, if packaged for repacking or for use in the manufacture of another drug:

(*a*) For all tests except sterility; 5 packages.

(*b*) For sterility testing; 10 packages.

Each such package shall contain approximately 2 milliliters taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(iii) If crystalline dihydrostreptomycin sulfate is used in making the batch; 2 immediate containers containing approximately 0.5 gram each, packaged in accordance with the requirements of § 146b.101 (b).

(iv) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (iii) of this paragraph, is required if such result or sample has been previously submitted.

(5) In connection with contemplated requests for certification of repackaged batches or batches of another drug in the manufacture of which it is to be used, the manufacturer of the batch which is to be so repacked or used may request the Commissioner to make check tests and assays on a sample of such batch, taken as prescribed by subparagraph (3) (ii) of this paragraph. From the information required by subparagraph (2) (i) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(e) *Fees.* The fee for the services rendered with regard to each batch under the regulations in this part shall be:

(1) $10.00 for each immediate container in the samples submitted in accordance with paragraph (d) (3) (i) (*a*), (ii) (*a*), and (5) of this section; $4.00 for each package in the sample submitted in accordance with paragraph (d) (3) (iii) and (iv) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146b.107 *Streptomycin-polymyxin-bacitracin tablets*—(a) *Standards of identity, strength, quality, and purity.* Streptomycin-polymyxin-bacitracin tablets are tablets composed of streptomycin, polymyxin B, and bacitracin, with or without the addition of one or more suitable and harmless buffer substances, diluents, binders, lubricants, colorings, and flavorings. The potency of each tablet is not less than 250 mg. of streptomycin, 200,000 units of polymyxin B, and 5,000 units of bacitracin. Its moisture content is not more than 3%. The streptomycin used conforms to the standards prescribed therefor by § 146b.101 (a), except subparagraphs (2) and (4) of that paragraph. The polymyxin used is produced by the growth of Bacillus polymyxa, has a potency of not less than 3,800 units per milligram, and it is nontoxic. The bacitracin used conforms to the standards prescribed therefor by § 146e.401 (a) of this chapter, except subparagraphs (1), (2), and (4) of that paragraph, but its potency is not less than 30 units per milligram. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each tablet is enclosed in a foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the tablets by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear, on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams of streptomycin in each tablet of the batch;

(iii) The number of units of polymyxin B in each tablet of the batch;

(iv) The number of units of bacitracin in each tablet of the batch; and

(v) The statement "Expiration date ------," the blank being filled in with the date which is 18 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of streptomycin-polymyxin-bacitracin tablets shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless they were previously submitted) the dates on which the latest assays of the streptomycin, polymyxin, and bacitracin used in making such batch were completed, the potency of each tablet, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency of streptomycin, polymyxin, and bacitracin per tablet, and average moisture.

(ii) The streptomycin used in making the batch; potency, toxicity, histamine, moisture, and pH.

(iii) The polymyxin used in making the batch; potency and toxicity.

(iv) The bacitracin used in making the batch; potency, toxicity, moisture, and pH.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one tablet for each 5,000 tablets in the batch, but in no case less than 30 tablets or more than 100 tablets, collected by taking single tablets at such intervals throughout the entire time of tableting that the quantities tableted during the intervals are approximately equal.

(ii) The streptomycin used in making the batch; five packages containing approximately equal portions of not less than 0.5 gram each, packaged in accordance with the requirements of § 146b.101 (b).

(iii) The polymyxin used in making the batch; five packages, each containing approximately equal portions of not less than 0.5 gram.

(iv) The bacitracin used in making the batch; six packages, each containing approximately equal portions of not less than 0.5 gram, packaged in accordance with the requirements of § 146e.401 (b) of this chapter.

(v) In case of an initial request for certification, each other ingredient used in making the batch; one package of each, containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii), (iii), and (iv) of this paragraph, and no sample referred to in subparagraph (3) (ii), (iii), and (iv) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of streptomycin-polymyxin-bacitracin tablets under the regulations in this part shall be:

(1) $1.00 for each tablet in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii), (iii), (iv), and (v) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such tablets and packages are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146b.108 *Streptomycin syrup, streptomycin and kaolin in gel; dihydrostreptomycin syrup, dihydrostreptomycin and kaolin in gel*—(a) *Standards of identity, strength, quality and purity.* Streptomycin syrup and dihydrostreptomycin syrup are streptomycin or dihydrostreptomycin dissolved in a suitable and harmless diluent that contains one or more suitable and harmless preservatives. Streptomycin and kaolin in gel and dihydrostreptomycin and kaolin in gel are streptomycin or dihydrostreptomycin dissolved or suspended in a suitable and harmless gel base that contains kaolin and one or more suitable and harmless preservatives, with or without one or more suitable and harmless suspending, dispersing, or flavoring agents and with or without pectin, bismuth glycolylarsanilate, bismuth magma, suitable mineral salts, or procaine hydrochloride. Its potency is not less than 10 milligrams per milliliter. The streptomycin used conforms to the standards prescribed therefor by § 146b.101 (a), except subparagraphs (2), (4), and (6) of that paragraph. The dihydrostreptomycin used conforms to the standards prescribed therefor by § 146b.103, except the standards for sterility, pyrogens, and moisture. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate container shall be glass, so closed as to be a tight container as defined by the U. S. P. and of such composition that will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams of streptomycin or dihydrostreptomycin in each milliliter of the batch;

(iii) The statement, "Expiration date ____________," the blank being filled in with the date which is 18 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 36 months after the month during which the batch was certified, if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) The name and quantity of each preservative used; and

(v) If it contains pectin, kaolin, bismuth magma, bismuth glycolylarsanilate, mineral salts, or procaine hydrochloride, the quantity of each such ingredient used and the name of the gel base.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the label and labeling, if it contains bismuth glycolylarsanilate, bismuth magma, or procaine hydrochloride, after the name "streptomycin and kaolin in gel" or "dihydrostreptomycin the kaolin in gel," wherever it appears, the words "with bismuth glycolylarsanilate" or "with bismuth magma" or "with procaine hydrochloride," in juxtaposition with such name.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the streptomycin or dihydrostreptomycin used in making the batch was completed, the potency per milliliter of the batch, the quantity of each ingredient used in making the batch, the date on which the latest assay comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per milliliter.

(ii) The streptomycin or dihydrostreptomycin used in making the batch; potency, toxicity, histamine content, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers or more than 12 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The streptomycin or dihydrostreptomycin used in making the batch; five packages containing approximately equal portions of not less than 0.5 gram each packaged in accordance with the requirements of § 146b.101 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each package in the sample submitted in accordance with paragraph (d) (3) (i) and (iii) of this section; $10.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) of this section; and

(2) If the Commissioner considers that investigations other than examinations of such packages are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146b.109 *Streptomycin-bacitracin-polymyxin gauze pads*—(a) *Standards of identity, strength, quality, and purity.* Streptomycin-bacitracin-polymyxin gauze pads are absorbent gauze that is impregnated with streptomycin, bacitracin, and polymyxin B. Each square inch of such pad shall contain not less than 1 milligram of streptomycin, 50 units of bacitracin, and 1,000 units of polymyxin B. It is sterile. Its moisture content is not more than 5 percent. The streptomycin used conforms to the standards prescribed therefor by § 146b.101 (a), except subparagraphs (2), (4), and (5) of that paragraph. The bacitracin used conforms to the standards prescribed therefor by § 146e.401 (a) of this chapter, except subparagraphs (1), (2), and (4) of that paragraph, but its potency is not less than 30 units per milligram. The polymyxin used conforms to the standards prescribed therefor by § 146b.107 (a). The absorbent gauze used conforms to the standards prescribed therefor by the U. S. P.

(b) *Packaging.* Unless it is intended solely for hospital use, and is conspicuously so labeled, each streptomycin-bacitracin-polymyxin gauze pad shall be packaged individually. In all cases the immediate container shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams of streptomycin in each pad of the batch;

(iii) The number of units of bacitracin in each pad of the batch;

(iv) The number of units of polymyxin B in each pad of the batch;

(v) The length, width, and type of gauze contained in the pad; and

(vi) The statement "Expiration date ____________," the blank being filled in with the date which is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 24 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the immediate container, the statement "Sterility of the pad cannot be guaranteed if the package bears evidence of damage or has been previously opened."

(3) On the circular or other labeling within or attached to the package, directions and precautions adequate for the use of such pads.

(d) *Request for certification; samples.* (1) In addition to complying with requirements of § 146.2 of this chapter, a person who requests certification of a batch of streptomycin-bacitracin-polymyxin gauze pads shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch marks and (unless they were previously submitted) the dates on which the latest assays of the streptomycin, bacitracin, and polymyxin used in making such batch were completed, the potency of each pad in the batch, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that the absorbent gauze used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency of streptomycin, bacitracin, and polymyxin per pad, sterility, and average moisture.

(ii) The streptomycin used in making the batch; potency, toxicity, moisture, and pH.

(iii) The bacitracin used in making the batch; potency, toxicity, moisture, and pH.

(iv) The polymyxin used in making the batch; potency and toxicity.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility; one pad for each 5,000 pads in the batch, but in no case less than 30 or more than 100 pads.

(*b*) For sterility testing; 10 pads.

Such samples shall be collected by taking single pads at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The streptomycin used in making the batch; five packages, each containing approximately equal portions of not less than 0.5 gram, packaged in accordance with the requirements of § 146b.101 (b).

(iii) The bacitracin used in making the batch; six packages, each containing approximately equal portions of not less than 0.5 gram, packaged in accordance with the requirements of § 146c.401 (b) of this chapter.

(iv) The polymyxin used in making the batch; five packages, each containing approximately equal portions of not less than 0.5 gram.

(v) In case of an initial request for certification, one package consisting of approximately 5 linear yards, or the equivalent, of the absorbent gauze used.

(4) No result referred to in subparagraph (2) (ii), (iii), and (iv) of this paragraph, and no sample referred to in subparagraph (3) (ii), (iii), and (iv) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $1.00 for each pad in the sample submitted in accordance with paragraph (d) (3) (i) (*a*) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii), (iii), (iv), and (v) of this section.

(2) If the Commissioner considers that investigations, other than examination of such pads and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146b.110 *Streptomycin otic with antifungal agent, streptomycin otic with ________; dihydrostreptomycin otic with antifungal agent, dihydrostreptomycin otic with ________ (the blank being filled in with the common or usual name of the antifungal agent)*—(a) *Standards of identity, strength, quality, and purity.* Streptomycin otic with antifungal agent or dihydrostreptomycin otic with antifungal agent is streptomycin or dihydrostreptomycin and one or more suitable antifungal agents and buffer substances, with or without one or more suitable and harmless preservatives, dissolved or suspended in a suitable and harmless vehicle. Its potency is not less than 2.5 milligrams per milliliter. Its pH is not less than 4.8 and not more than 6.0. The streptomycin used conforms to the standards prescribed therefor by § 146b.101 (a), except subparagraphs (2), (4), (5), and (6) of that paragraph. The dihydrostreptomycin used conforms to the standards prescribed therefor by § 146b.103 (a), except the standards for sterility, pyrogens, histamine, and moisture. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate container shall be glass, so closed as to be a tight container as defined by the U. S. P., and of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of milligrams of streptomycin or dihydrostreptomycin in each milliliter of the batch.

(iii) The name and quantity of each antifungal agent and preservative used.

(iv) The statement "Expiration date ________," the blank being filled in with the date which is 24 months after the month during which the batch was certified, except that the blank may be filled in with the date that is 36 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug as prepared by him is stable for such period of time: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is

conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the streptomycin or dihydrostreptomycin used in making the batch was completed, the potency per milliliter of the batch, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch, and a statement that each such ingredient conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per milliliter, pH.

(ii) The streptomycin or dihydrostreptomycin used in making the batch; potency, toxicity, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin sulfate.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 or more than 12 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The streptomycin or dihydrostreptomycin used in making the batch; 5 packages, each containing approximately equal portions of not less than 0.5 gram, packaged in accordance with the requirements of § 146b.101 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch; 1 package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i), (ii), and (iii) of this section.

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations. The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146b.111 *Streptomycin-kaolin-pectin-aluminum hydroxide gel powder veterinary; dihydrostreptomycin-kaolin-pectin-aluminum hydroxide gel powder veterinary*—(a) *Standards of identity, strength, quality, and purity.* Streptomycin-kaolin-pectin-aluminum hydroxide gel powder veterinary and dihydrostreptomycin-kaolin-pectin-aluminum hydroxide gel powder veterinary is streptomycin or dihydrostreptomycin, kaolin, pectin, and dried aluminum hydroxide gel with or without the addition of one or more suitable and harmless diluents, colorings, and flavorings. Its content of streptomycin or dihydrostreptomycin is not less than 37.5 milligrams per gram of powder. Its moisture content is not more than 10 percent. The streptomycin used conforms to the standards prescribed therefor by § 146b.101 (a), except subparagraphs (2) and (4) of that paragraph. The dihydrostreptomycin used conforms to the standards prescribed therefor by § 146b.103, except the standards for sterility and pyrogens. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limits therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of milligrams of streptomycin or dihydrostreptomycin per gram in the immediate containers.

(iii) The quantity of kaolin, pectin, and aluminum hydroxide per gram in the immediate container.

(iv) The statement "Expiration date ----------," the blank being filled in with the date which is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 24 months after the month in which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(v) The statement "For veterinary use only."

(2) On the circular or other labeling within or attached to the package, directions and precautions adequate for the use of such powder, including:

(i) Clinical indications.

(ii) Dosage and administration.

(iii) Contraindications.

(iv) Untoward effects that may accompany administration.

If two or more such immediate containers are in such package, the number of circulars or other labeling shall not be less than the number of such containers.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the streptomycin or dihydrostreptomycin used in making such batch was completed, the potency per gram of powder, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per gram of powder and average moisture.

(ii) The streptomycin or dihydrostreptomycin used in making the batch; potency, toxicity, histamine content, moisture, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin sulfate.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 containers in the batch, but in no case less than 20 such containers or more than 100 immediate containers, unless each such container is packaged to contain more than 1.0 gram, in which case the sample shall consist of 1.0 gram for each 5,000 immediate containers in the batch, but in no case less than 20 grams or more than 100 grams. Such samples shall be collected by taking single immediate containers or 1.0-gram portions at such intervals throughout the entire time the containers are being filled that the quantities packaged during the intervals are approximately equal.

(ii) The streptomycin or dihydrostreptomycin used in making the batch; 5 packages containing approximately equal portions of not less than 0.5 gram each, packaged in accordance with the requirements of § 146b.101 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5.0 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the service rendered with respect to each batch under the regulations in this part shall be:

(1) $1.00 for each immediate container in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $10.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (iii) of this section.

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification, unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146b.112 *Streptomycin for inhalation therapy; dihydrostreptomycin for inhalation therapy*—(a) *Standards of identity, strength, quality, and purity.* Streptomycin for inhalation therapy and dihydrostreptomycin for inhalation therapy are streptomycin or dihydrostreptomycin, with or without one or more suitable and harmless diluents. The streptomycin used conforms to the requirements of § 146b.101 (a), except § 146b.101 (a) (2) and (4), and except that if it is packaged with inert gases its moisture content is not more than 0.5 percent. The dihydrostreptomycin used conforms to the requirements of § 146b.103 (a), except the standards for sterility and pyrogens, and except that if it is packaged with inert gases its moisture content is not more than 0.5 percent. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* The immediate container of streptomycin for inhalation therapy and dihydrostreptomycin for inhalation therapy shall be a tight container as defined by the U. S. P.; its closure shall be one through which a hypodermic needle cannot be introduced; and the container shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each such container shall contain not less than 50 milligrams, and may contain one or more suitable and harmless inert gases or each may be packaged in combination with a container of a suitable and harmless solvent.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of milligrams in the immediate container, or (if it is packaged with one or more inert gases), the number of grams that shall be ejected when used as directed in the labeling.

(iii) The statement "Expiration date -----," the blank being filled in with the date which is 24 months if it is packaged with inert gasses, or 48 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(iv) The statement "Warning—Not for injection."

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing, and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of streptomycin for inhalation therapy or dihydrostreptomycin for inhalation therapy shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of milligrams in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising such batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency and moisture if the streptomycin or dihydrostreptomycin has been previously submitted, or for potency, toxicity, moisture, pH, histamine content, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin, if the streptomycin or dihydrostreptomycin has not been previously submitted. If such batch, or any part hereof, is to be packaged in combination with a container of a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) Such person shall submit with his request accurately representative samples of the following:

(i) The batch:

(*a*) If the streptomycin or dihydrostreptomycin used has been previously submitted; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers (or if it is packaged with inert gases, not less than 7 immediate containers and not more than 12 immediate containers), or more than 12 immediate containers.

(*b*) If the streptomycin or dihydrostreptomycin used has not been previously submitted; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 12 immediate containers or more than 25 immediate containers.

Such sample shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) If it is packaged with inert gases and the streptomycin or dihydrostreptomycin used has not been previously submitted; 5 packages containing approximately equal portions of not less than 0.5 gram each, packaged in accordance with the requirements of § 146b.101 (b).

(iii) In case of an initial request for the certification of a batch which is to be packaged in combination with a solvent which is not recognized by the U. S. P., or when any change is made in the composition of such solvent, five packages of the solvent included in the combination.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (2) (i) and (ii) of this section.

(2) If the Commissioner considers that investigations other than examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

(f) *Exemption of streptomycin for inhalation therapy and dihydrostreptomycin for inhalation therapy for veterinary use from certification.* Streptomycin for inhalation therapy and dihydrostreptomycin for inhalation therapy that conform to the requirements of paragraphs (a), (b), and (c) of this section shall be exempt from the requirements of section 502 (l) and 507 of the act, if they comply with all the following conditions:

(1) They are intended solely for veterinary use and are conspicuously so labeled.

(2) The labels bear an expiration date that is not more than 48 months after the month during which the batch was last assayed and released by the manufacturer, except that such date is not more than 24 months if it is packaged with inert gases.

(3) The circular or other labeling within or attached to the package bears information that the antibiotics are for use only in the prevention or treatment of chronic respiratory disease (air-sac infection) in chickens and bears directions and warnings adequate for such use.

§ 146b.113 *Dihydrostreptomycin-streptomycin sulfates*—(a) *Standards of identity, strength, quality, and purity.* Dihydrostreptomycin-streptomycin sulfates is a mixture of equal parts of dihydrostreptomycin sulfate and streptomycin sulfate. It is so purified and dried that:

(1) It is sterile.

(2) It is nontoxic.

(3) It is nonpyrogenic.

(4) It contains no histamine or histamine like substance.

(5) Its moisture content is not more than 5 percent.

(6) Its pH in an aqueous solution containing 0.1 gram of dihydrostreptomycin and 0.1 gram of streptomycin per milliliter is not less than 4.5 and not more than 7.0.

The dihydrostreptomycin sulfate used conforms to the standards prescribed by § 146b.103, except the standards for streptomycin content. The streptomycin sulfate used conforms to the standards prescribed by § 146b.101 (a).

(b) *Packaging.* It shall be packaged in accordance with the requirements prescribed by § 146b.101 (b), except that in case it is packaged for dispensing each immediate container shall contain not less than 0.5 gram of dihydrostreptomycin and 0.5 gram of streptomycin or multiples of each such salt up to and including 5.0 grams of dihydrostreptomycin and 5.0 grams of streptomycin.

(c) *Labeling.* It shall be labeled in accordance with the requirements prescribed by § 146b.101 (c), except that each package shall bear on the outside wrapper or container and the immediate container the number of grams of dihydrostreptomycin, the number of grams of streptomycin and the total number of grams of both salts in the immediate container.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch marks, and (unless they were previously submitted) the dates on which the latest assays of the dihydrostreptomycin and streptomycin used in making the batch were completed, the content of dihydrostreptomycin and streptomycin in each container, and the date on which the latest assay of the drug comprising such batch was completed. If such batch or any part thereof is to be packaged with a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements described therefor by this section.

(2) Except as otherwise provided by subparagraph (5) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following made by him on an accurately representative sample of:

(i) The batch; content of dihydrostreptomycin and streptomycin, sterility, toxicity, pyrogens, histamine content, moisture, and pH.

(ii) The dihydrostreptomycin and streptomycin used in making the batch; potency, and if crystalline dihydrostreptomycin is used, crystallinity.

(3) Except as otherwise provided by subparagraph (5) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility; one immediate container for each 5,000 immediate containers in the batch but in no case less than 6 or more than 12 immediate containers.

(*b*) For sterility testing; 10 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The dihydrostreptomycin used in making the batch; 2 packages, each containing approximately equal portions of not less than 0.5 gram, packaged in accordance with the requirements of § 146b.101 (b).

(iii) The streptomycin used in making the batch; one package containing approximately 0.5 gram packaged in accordance with the requirements of § 146b.101 (b).

(4) If such batch is packaged for repacking, such person shall submit with his request a sample consisting of the following:

(i) For all tests except sterility: 6 packages.

(ii) For sterility testing: 10 packages. Each such package shall contain not less than 0.5 gram of dihydrostreptomycin and 0.5 gram of streptomycin taken from different parts of such batch, and each shall be packaged in accordance with the requirements of § 146b.101 (b).

(5) No result referred to in subparagraph (2) of this paragraph, and no sample referred to in subparagraphs (3) (ii) and (iii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $10.00 for each immediate container in the samples submitted in accordance with paragraph (d) (3) (i) (*a*) and (4) (i) of this section; $4.00 for each sample submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations other than examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for issuance of a certificate, the cost of such investigations. The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146b.114 *Streptomycin sulfate oral veterinary*—(a) *Standards of identity, strength, quality, and purity.* Streptomycin sulfate oral veterinary is the sulfate salt of a kind of streptomycin or a mixture of two or more such salts. Each such drug is so purified and dried that:

(1) Its potency is not less than 450 micrograms per milligram.

(2) It is nontoxic.

(3) Its moisture content is not more than 14.0 percent.

(4) Its pH in aqueous solution of 0.2 gram per milliliter is not less than 3.0 and not more than 7.0.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of streptomycin sulfate oral veterinary shall bear on its outside wrapper or container and the immediate container:

(1) The batch mark.

(2) The number of milligrams of streptomycin per gram and the number of grams of the drug in the immediate container.

(3) The statement "Expiration date ______________," the blank being filled in with the date which is 36 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(4) The statement "For use only in the manufacture of oral veterinary drugs."

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of milligrams of streptomycin per gram, and the total number of grams of streptomycin in each package. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, toxicity, moisture, and pH.

(2) Such person shall submit with his request an accurately representative sample of the batch, consisting of 5 packages each containing approximately 1.0 gram taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) (2) of this section.

(2) If the Commissioner considers that investigations, other than the examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146b.115 *Streptomycin sulfate powder oral veterinary; streptomycin sulfate granules oral veterinary*—(a) *Standards of identity, strength, quality, and purity.* Streptomycin sulfate powder oral veterinary or streptomycin sulfate granules oral veterinary is streptomycin sulfate oral veterinary with one or more suitable and harmless diluents and stabilizing agents. Its potency is not less than 333 micrograms per milligram. Its moisture content is not more than 7.0 percent. The streptomycin sulfate oral veterinary used conforms to the standards prescribed by § 146b.114 (a) Each other ingredient used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P. The composition of the immediate containers shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of milligrams of streptomycin per gram and the number of grams in the immediate container.

(iii) The statement "Expiration date ---------------," the blank being filled in with the date which is 36 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(iv) The statement "For oral veterinary use only."

(v) The statement "For manufacturing use," "For repacking," or "For manufacturing use or repacking," when packaged for repacking or for use as an ingredient in the manufacture of another drug, as the case may be.

(2) On the circular or other labeling within or attached to the package, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the streptomycin sulfate oral veterinary used in making such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each other ingredient used conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency and moisture.

(ii) The streptomycin sulfate oral veterinary used in making the batch; potency, toxicity, moisture, and pH.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers or more than 12 immediate containers, unless each such container is packaged to contain more than 15 grams, in which case the sample shall consist of 15 grams for each 5,000 immediate containers in the batch, but in no case less than five 15-gram portions or more than twelve 15-gram portions. Such samples shall be collected by taking single immediate containers or 15-gram portions at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The streptomycin sulfate oral veterinary used in making the batch; 5 packages containing approximately equal portions of not less than 1.0 gram each, packaged in accordance with the requirements of § 146b.114 (b).

(iii) In case of an initial request for certification, the other ingredients used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (3) (i), (ii), and (iii) of this section; and

(2) If the Commissioner considers that investigations other than the examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

(f) *Exemption of streptomycin sulfate powder oral veterinary and streptomycin sulfate granules oral veterinary from certification.* Streptomycin sulfate powder oral veterinary and streptomycin sulfate granules oral veterinary that conform to the requirements of paragraphs (a) (except that they may contain one or more essential vitamin and mineral substances for nutritive purposes), (b), and (c) of this section shall be exempt from the requirements of sections 502 (l) and 507 of the act, if they comply with all the following conditions:

(1) The labels bear an expiration date that is not more than 36 months after the month during which the batch was last assayed and released by the manufacturer.

(2) If they contain added vitamins or minerals, the labels bear the name and quantity of each such substance and a statement that such substances are present only for furnishing additional vitamins and minerals while animals are eating less feed.

(3) The labels bear a statement that solutions prepared with the drugs are stable for not more than 24 hours.

(4) The circular or other labeling within or attached to the package bears information that only the antibiotics are intended for the prevention or treatment of the following conditions, and further, bears directions and warnings adequate for such use:

(i) Bacterial enteritis in swine.

(ii) Bacterial calf scours.

(iii) Chronic respiratory disease (air-sac infection) in chickens.

(iv) Blue comb (mud fever, nonspecific infectious enteritis) in poultry.

§ 146b.116 *Streptomycylidene isonicotinyl hydrazine sulfate*—(a) *Standards of identity, strength, quality, and purity.* Streptomycylidene isonicotinyl hydrazine sulfate is the crystalline sulfate compound of streptomycin and isonicotinic acid hydrazide. It is so purified and dried that:

(1) It contains not less than the equivalent of 583 micrograms of streptomycin per milligram and its isonicotinic acid hydrazide equivalent content is not less than 13.75 percent.

(2) It is sterile.

(3) It is nontoxic.

(4) It is nonpyrogenic.

(5) It contains no histamine nor histamine-like substance.

(6) Its moisture content is not more than 5 percent.

(7) Its pH in an aqueous solution containing the equivalent of 0.2 gram of streptomycin per milliliter is not less than 4.5 and not more than 7.5.

(8) Its extinction coefficient $E^{1\%}_{1\,\text{cm.}}$ is not less than 150 at 260 millimicrons.

The streptomycin used conforms to the requirements of § 146b.101 (a). The isonicotinic acid hydrazide used has a purity of not less than 98 percent and it has a melting point of not less than 169° C. and not more than 172° C.

(b) *Packaging.* It shall be packaged in accordance with the requirements of § 146b.101 (b), except that each immediate container shall contain the equivalent of not less than 1.0 gram of streptomycin.

(c) *Labeling.* It shall be labeled in accordance with the requirements of § 146b.101 (c), except that in lieu of the labeling prescribed by subparagraph (1) (ii) of paragraph (c) each package shall bear on the outside wrapper or container and the immediate container the number of grams of equivalent streptomycin activity, the equivalent number of grams of isonicotinic acid hydrazide, and the number of grams of streptomycylidene isonicotinyl hydrazine sulfate in the immediate container, and its expiration date shall be 36 months after the month during which the batch was certified.

(d) *Request for certification, check tests and assays; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of grams of streptomycin, isonicotinic acid hydrazide, and streptomycylidene isonicotinyl hydrazine sulfate in each package and (unless it was previously submitted) the date on which the latest assay of the drug comprising such batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, sterility, toxicity, pyrogens, histamine content, moisture, pH, crystallinity, and extinction coefficient. If such batch or any part thereof is to be packaged with a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) If such batch is packaged for dispensing, such person shall submit in connection with his request an accurately representative sample of the batch, consisting of the following:

(i) For all tests except sterility; one immediate container for each 5,000 immediate containers in such batch, but in no case less than six or more than 12 immediate containers.

(ii) For sterility testing; 10 immediate containers.

Such sample shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(3) If such batch is packaged for repacking or for use in the manufacture of another drug, such person shall submit with his request an accurately representative sample of the batch, consisting of the following:

(i) For all tests except sterility; six packages, each containing the equivalent of approximately 1 gram of streptomycin activity.

(ii) For sterility testing; 10 packages, each containing the equivalent of approximately 0.5 gram of streptomycin activity.

Each such package shall be taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(4) In connection with contemplated requests for certification of repackaged batches or batches of another drug in the manufacture of which it is to be used, the manufacturer of the batch which is to be so repacked or used may request the Commissioner to make check tests and assays on a sample of such batch, taken as prescribed by subparagraph (3) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted tests and results of assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $10.00 for each immediate container in the samples submitted in accordance with paragraph (d) (2) (i), (3) (i), and (4) of this section.

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146b.117 *Dihydrostreptomycin-streptomycin sulfates solution*—(a) *Standards of identity, strength, quality, and purity.* Dihydrostreptomycin-streptomycin sulfates solution is an aqueous solution of dihydrostreptomycin-streptomycin sulfates. Such solution conforms to all standards prescribed by § 146b.113 (a) for dihydrostreptomycin-streptomycin sulfates, except the limitation on moisture content, and except that:

(1) Each milliliter shall contain not less than 200 milligrams each of dihydrostreptomycin and streptomycin and not more than 250 milligrams each of dihydrostreptomycin and streptomycin, unless it is intended solely for veterinary use and is conspicuously so labeled.

(2) It may contain suitable and harmless buffer substances, preservatives, and stabilizing agents. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(3) Its pH is not less than 5.0 and not more than 7.5.

(b) *Packaging.* It shall be packaged in accordance with the requirements of § 146b.106 (b).

(c) *Labeling.* It shall be labeled in accordance with the requirements of § 146b.106 (c) for streptomycin sulfate solution, except in lieu of subparagraph (1) (ii) of that paragraph each package shall bear on the outside wrapper or container and the immediate container the number of grams of dihydrostreptomycin, the number of grams of streptomycin, and the total number of grams of both salts in each milliliter in the immediate container.

(d) *Request for certification; samples.* In addition to complying with the requirements of § 146b.113 (d), a person who requests certification of a batch shall submit in connection with his initial request one package containing approximately 5.0 grams of each other ingredient used in making the batch.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be the same as those prescribed by § 146b.113 (e), except that the fee for each immediate container in the sample of other ingredients required by paragraph (d) of this section shall be $4.00.

§ 146b.118 *Streptomycin-penicillin-sulfonamide with kaolin and pectin; dihydrostreptomycin-penicillin-sulfonamide with kaolin and pectin*—(a) *Standards of identity, strength, quality, and purity.* Streptomycin-penicillin-sulfonamide with kaolin and pectin and dihydrostreptomycin-penicillin-sulfonamide with kaolin and pectin are dry mixtures of streptomycin sulfate or dihydrostreptomycin sulfate, crystalline penicillin G (sodium or potassium), one or more suitable sulfonamides, kaolin, and pectin, with or without bismuth subcarbonate and with or without one or more suitable and harmless preservatives, colorings, and flavorings. Its moisture content is not more than 2 percent. The pH of a suspension prepared as directed in its labeling is not less than 5.5 and not more than 7.5. The streptomycin used conforms to the standards prescribed therefor by § 146b.101 (a), except subparagraphs (2) and (4) of that paragraph. The dihydrostreptomycin used conforms to the standards prescribed therefor by § 146b.103, except the standards for sterility and pyrogens. The crystalline penicillin G used conforms to the standards prescribed therefor by § 146a.24 (a) of this chapter, except subparagraphs (2) and (4) of that paragraph. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P. and shall contain not less than 1.0 gram of streptomycin or dihydrostreptomycin and not less than 1,200,000 units of penicillin. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of grams of streptomycin or dihydrostreptomycin and the number of units of penicillin in the immediate container.

(iii) The name and quantity of each sulfonamide in the immediate container.

(iv) The quantity of kaolin and pectin in the immediate container.

(v) If the batch contains bismuth subcarbonate or preservatives, the name and quantity of each such substance in the immediate container.

(vi) The statement "Expiration date ------," the blank being filled in with the date which is 24 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(vii) The statement "Warning—Not for injection."

(2) On the immediate container, directions for preparing the suspension and the statement "Suspension may be kept in refrigerator for 1 week without significant loss of potency."

(3) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch marks and (unless they were previously submitted) the dates on which the latest assays of the streptomycin or dihydrostreptomycin and penicillin used in making such batch were completed, the number of grams of streptomycin or dihydrostreptomycin and the number of units of penicillin in the immediate container, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; content of streptomycin or dihydrostreptomycin, content of penicillin, moisture, and pH.

(ii) The streptomycin or dihydrostreptomycin used in making the batch; potency, toxicity, histamine content, moisture, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin.

(iii) The penicillin used in making the batch; potency, toxicity, moisture, pH, crystallinity, heat stability, and penicillin G content.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 6 or more than 12 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time the containers are being filled that the quantities packaged during the intervals are approximately equal.

(ii) The streptomycin or dihydrostreptomycin used in making the batch; 5 packages, containing approximately equal portions of not less than 0.5 gram each, packaged in accordance with the requirements of § 146b.101 (b).

(iii) The penicillin used in making the batch; 10 packages, containing approximately equal portions of not less than 60 milligrams each, packaged in accordance with the requirements of § 146a.24 (b).

(iv) In case of an initial request for certification, each other ingredient used in making the batch; one package of each, containing approximately 5.0 grams.

(4) No result referred to in subparagraph (2) (ii) and (iii) of this paragraph, and no sample referred to in subparagraph (3) (ii) and (iii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (3) (i), (iii), and (iv) of this section; $10.00 for each package in the sample submitted in accordance with paragraph (d) (3) (ii) of this section.

(2) If the Commissioner considers that investigations other than examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification, unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146b.119 *Streptomycin hydrochloride solution oral veterinary; streptomycin sulfate solution oral veterinary*—(a) *Standards of identity, strength, quality, and purity.* Streptomycin hydrochloride solution oral veterinary and streptomycin sulfate solution oral veterinary are aqueous solutions of streptomycin hydrochloride or streptomycin sulfate, with one or more suitable and harmless preservatives. The drug may also contain one or more suitable and harmless buffer substances and stabilizing agents. Its potency is not less than 250 milligrams per milliliter. Its pH is not less than 5.0 and not more than 8.0. It is nontoxic. Each preservative, buffer substance, and stabilizing agent used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on the outside wrapper or container and the immediate container:

(1) The batch mark.

(2) The number of milligrams of streptomycin in each milliliter of the immediate container.

(3) The statement "Expiration date ______," the blank being filled in with the date which is 12 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(4) The name and quantity of each preservative used.

(5) The statement "For oral veterinary use only."

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, and the number of milligrams of streptomycin per milliliter. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, toxicity, and pH.

(2) Such person shall also submit with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 or more than 12 immediate containers.

(ii) In case of an initial request for certification, each other ingredient used in making the batch; 1 package of each containing approximately 5 grams.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) (2) of this section.

(2) If the Commissioner considers that investigations other than the examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

(f) *Exemption of streptomycin hydrochloride solution oral veterinary and streptomycin sulfate solution oral veterinary from certification.* Streptomycin hydrochloride solution oral veterinary and streptomycin sulfate solution oral veterinary that conform to the requirements of paragraphs (a) (except that they may contain one or more essential vitamin and mineral substances for nutritive purposes), (b), and (c) of this section shall be exempt from the requirements of sections 502 (l) and 507 of the act, if they comply with all the following conditions:

(1) The labels bear an expiration date that is not more than 12 months after the month during which the batch was last assayed and released by the manufacturer.

(2) If they contain added vitamins or minerals, the labels bear the name and quantity of each such substance and a statement that such substances are present only for furnishing additional vitamins and minerals while animals are eating less feed.

(3) The labels bear a statement that solutions prepared with the drugs are stable for not more than 24 hours.

(4) The circular or other labeling within or attached to the package bears information that only the antibiotics are intended for the prevention or treatment of the following conditions, and further, bears directions and warnings adequate for such use:

(i) Bacterial enteritis in swine.

(ii) Bacterial calf scours.

(iii) Chronic respiratory disease (airsac infection) in chickens.

(iv) Blue comb (mud fever, nonspecific infectious enteritis) in poultry.

§ 146b.120 *Dihydrostreptomycin-streptomycin sulfates with isonicotinic acid hydrazide.* Dihydrostreptomycin-streptomycin sulfates with isonicotinic acid hydrazide conforms to all requirements and is subject to all procedures prescribed by § 146b.113 for dihydrostreptomycin-streptomycin sulfates, except that:

(a) It contains not less than 100 milligrams of isonicotinic acid hydrazide for each 0.5 gram of dihydrostreptomycin-streptomycin sulfates. The isonicotinic acid hydrazide used has a purity of not less than 98 percent and has a melting point of not less than 169° C. and not more than 172° C.

(b) In lieu of the directions prescribed by § 146b.113 (c), it shall be labeled in accordance with the requirements prescribed by § 146b.101 (c), except that each package shall bear on the outside wrapper or container and the immediate container the number of grams of dihydrostreptomycin, the number of grams of streptomycin and the number of grams of isonicotinic acid hydrazide, and the expiration date shall be 18 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(c) In addition to complying with the requirements of § 146b.113 (d), a person who requests certification of a batch shall submit with his request a statement showing the number of grams of isonicotinic acid hydrazide in each package, and in case of an initial request for certification, a sample consisting of approximately 5.0 grams of the isonicotinic acid hydrazide used in making the batch.

(d) The fee for the services rendered with respect to the sample of isonicotinic acid hydrazide submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146b.121 *Streptomycin-erythromycin ointment*—(a) *Standards of identity, strength, quality, and purity.* Streptomycin-erythromycin ointment is streptomycin and erythromycin in a suitable and harmless ointment base, with or without one or more suitable sulfonamides and with or without suitable and harmless dispersing and suspending agents. Its moisture content is not more than 1.0 percent. It contains per gram not less than 3 milligrams of streptomycin and not less than 5 milligrams of erythromycin. The streptomycin used conforms to the requirements of § 146b.101 (a), except § 146b.101 (a) (2), (4), and (5). The erythromycin used is produced by the growth of Streptomyces erythreus, has a potency of not less than 850 micrograms per milligram (on the anhydrous basis), is nontoxic, has a moisture content of not more than 10 percent, its pH in a saturated aqueous solution is not less than 8 and not more than 10.5, and it gives a characteristic color test with acetone and hydrochloric acid. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Streptomycin-erythromycin ointment shall be packaged in collapsible tubes which shall be well-closed containers as defined by the U. S. P. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of milligrams of streptomycin and the number of milligrams of erythromycin in each gram or milliliter of the batch.

(iii) If it contains one or more sulfonamides, the name and quantity of each such ingredient in each gram or milliliter of the batch.

(iv) The statement "For veterinary use only."

(v) The statement "Expiration date ______," the blank being filled in with the date that is 12 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the label and labeling, if it contains one or more sulfonamides, after the name "streptomycin-erythromycin ointment," wherever it appears, the words "with sulfonamide(s)," in juxtaposition with such name.

(3) On the circular or other labeling within or attached to the package, adequate directions and warnings for the veterinary use of such drug by the laity.

Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless they were previously submitted) the dates on which the latest assays of the streptomycin and erythromycin used in making such batch were completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch: Potency and moisture.

(ii) The streptomycin and erythromycin used in making the batch: Potency, toxicity, pH, moisture, and color-identity test, if it is erythromycin.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch: 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 6 immediate containers or more than 12 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The streptomycin used in making the batch: 5 packages containing approximately equal portions of not less than 0.5 gram each, packaged in accordance with the requirements of § 146b.101 (b).

(iii) The erythromycin used in making the batch: 5 packages, each containing approximately equal portions of not less than 0.5 gram.

(iv) In case of an initial request for certification, the ingredients used in making the ointment base of the batch: 1 package of each, containing approximately 200 grams, except for the suspending or dispersing agents and sulfonamides used, in which case the sample shall consist of approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no samples referred to in subparagraph (3) (ii) and (iii) of this paragraph, is required if such result or samples have been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i), (ii), (iii), and (iv) of this section.

(2) If the Commissioner considers that investigations other than examination of such packages are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146b.122 *Streptomycin-chlortetracycline-chloramphenicol-bacitracin dental cement; dihydrostreptomycin-chlortetracycline-chloramphenicol-bacitracin dental cement*—(a) *Standards of identity, strength, quality, and purity.* Streptomycin - chlortetracycline - chloramphenicol-bacitracin dental cement and dihydrostreptomycin-chlortetracycline-chloramphenicol-bacitracin dental cement are streptomycin or dihydrostreptomycin, chlortetracycline, chloramphenicol, and bacitracin in a base composed of suitable and harmless inert inorganic salts and oxides. Its moisture content is not more than 1 percent. It contains not less than 1.0 milligram of streptomycin or dihydrostreptomycin, not less than 1.0 milligram of chlortetracycline, not less than 1.0 milligram of chloramphenicol, and not less than 50 units of bacitracin per gram. The streptomycin used conforms to the standards prescribed by § 146b.101 (a), except § 146b.101 (a) (2), (4), and (5). The dihydrostreptomycin used conforms to the standards prescribed by § 146b.103, except the standards for sterility, pyrogens, and histamine. The chlortetracycline used conforms to the standards prescribed by § 146c.201 (a) of this chapter, except § 146c.201 (a) (2), (4), and (5). The chloramphenicol used conforms to the standards prescribed by § 146d.301 (a) of this chapter, except § 146d.301 (a) (2), (4), and (5). The bacitracin used conforms to the standards prescribed by § 146e.401 (a) of this chapter, except § 146e.401 (a) (2) and (4). Each other ingredient used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Each batch of dental cement shall be packaged in immediate containers of transparent glass that meet the test for tight containers as defined by the U. S. P., and so sealed that the contents cannot be used without destroying such seal. The immediate container and closure shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of milligrams of streptomycin or dihydrostreptomycin, chlortetracycline, and chloramphenicol and the number of units of bacitracin in each gram of the batch.

(iii) The statement "Expiration date ________," the blank being filled in with the date that is 12 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container, the statement "Caution: Federal law prohibits dispensing without prescription."

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing, adequate directions and warnings for its use by practitioners licensed by law to administer such drug.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless they were previously submitted) the dates of the latest tests and assays of the streptomycin or dihydrostreptomycin, chlortetracycline, chloramphenicol, and bacitracin used in making the batch.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch: Potency and moisture.

(ii) The streptomycin or dihydrostreptomycin used in making the batch: Potency, toxicity, moisture, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin sulfate.

(iii) The chlortetracycline used in making the batch: Potency, toxicity, moisture, and pH.

(iv) The chloramphenicol used in making the batch: Potency, toxicity, pH, specific rotation, melting point, and extinction coefficient.

(v) The bacitracin used in making the batch: Potency, toxicity, moisture, and pH.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch: 1 package for each 500 packages in the batch, but in no case less than 6 packages nor more than 12 packages.

(ii) The streptomycin or dihydrostreptomycin used in making the batch: 5 packages containing approximately equal portions of not less than 0.5 gram.

(iii) The chlortetracycline used in making the batch: 10 packages, each containing approximately equal portions of not less than 60 milligrams.

(iv) The chloramphenicol used in making the batch: 10 packages, each containing approximately equal portions of not less than 300 milligrams.

(v) The bacitracin used in making the batch: 6 packages, each containing approximately equal portions of not less than 0.5 gram.

(vi) In case of an initial request for certification, each other ingredient used in making the batch: 1 package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii), (iii), (iv), and (v) of this paragraph, and no sample referred to in subparagraph (3) (ii), (iii), (iv), and (v) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i), (ii), (iii), (iv), (v), and (vi) of this section.

(2) If the Commissioner considers that investigations other than examination of such packages are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations. The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146b.123 *Streptomycin-sodium sulfathiazole solution veterinary; dihydrostreptomycin-sodium sulfathiazole solution veterinary*—(a) *Standards of identity, strength, quality, and purity.* Streptomycin-sodium sulfathiazole solution veterinary and dihydrostreptomycin-sodium sulfathiazole solution veterinary are streptomycin or dihydrostreptomycin and sodium sulfathiazole dissolved in a suitable and harmless vehicle. Each milliliter contains not less than 35 milligrams of streptomycin or dihydrostreptomycin and not less than 25 milligrams of sodium sulfathiazole. It is sterile. It is nontoxic. It is nonpyrogenic. It contains no histamine nor histamine-like substance. Its pH is not less than 5.0 and not more than 8.0. The streptomycin used conforms to the standards prescribed therefor by § 146b.101 (a), except subparagraph (6). The dihydrostreptomycin used conforms to the standards prescribed therefor by § 146b.103, except the standard for moisture. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging; labeling.* It shall be packaged and labeled in accordance with the requirements of § 146b.106 (b) and (c), except that in addition to the requirements of paragraph (c) each package shall bear on the outside wrapper or container and the immediate container:

(1) The composition of the vehicle.

(2) The number of milligrams of sodium sulfathiazole in each milliliter of the batch.

(3) The statement "For veterinary use only."

(c) *Requests for certification, samples; fees.* The person who requests certification of a batch shall submit in connection with his request the same information and number of samples for the batch as prescribed by § 146b.106 (d), and the fee for the services rendered with respect to each such batch shall be the same as that prescribed by § 146b.106 (e).

§ 146b.124 *Streptomycin-polymyxin-neomycin ointment; dihydrostreptomycin-polymyxin-neomycin ointment*—(a) *Standards of identity, stength, quality, and purity.* Streptomycin-polymyxin-neomycin ointment and dihydrostreptomycin-polymyxin-neomycin ointment are streptomycin or dihydrostreptomycin, polymyxin, and neomycin in a suitable and harmless ointment base, with or without one or more suitable sulfonamides, and with or without suitable and harmless dispersing and suspending agents. Its moisture content is not more than 1 percent. It contains not less than 8 milligrams of neomycin, not less than 8 milligrams of streptomycin or dihydrostreptomycin, and not less than 5,000 units of polymyxin B per gram of ointment. The streptomycin used conforms to the requirements of § 146b.101 (a), except § 146b.101 (a) (2), (4), and (5). The dihydrostreptomycin used conforms to the requirements of § 146b.103, except the standards for sterility, pyrogens, and histamine. The polymyxin B used conforms to the requirements prescribed for polymyxin B by § 146b.107 (a). The neomycin used conforms to the requirements prescribed for neomycin by § 146e.410 (a) (2) of this chapter. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Each batch of ointment shall be packaged in collapsible tubes which shall be well-closed containers as defined by the U. S. P. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of milligrams of streptomycin or dihydrostreptomycin, the number of milligrams of neomycin, and the number of units of polymyxin B in each gram of the batch.

(iii) If the batch contains one or more sulfonamides, the name and quantity of each such ingredient per gram of the batch.

(iv) The statement "For veterinary use only."

(v) The statement "Expiration date ________," the blank being filled in with the date that is 12 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the circular or other labeling within or attached to the package, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless they were previously submitted) the dates on which the latest assays of the streptomycin or dihydrostreptomycin, polymyxin B, and neomycin used in making such batch were completed; the quantity of each such ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following made by him on an accurately representative sample of:

(i) The batch: Potency and moisture.

(ii) The streptomycin or dihydrostreptomycin used in making the batch: Potency, toxicity, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin sulfate.

(iii) The polymyxin B used in making the batch: Potency and toxicity.

(iv) The neomycin used in making the batch: Potency, toxicity, moisture, and pH.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch: 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 7 immediate containers or more than 12 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The streptomycin or dihydrostreptomycin used in making the batch: 5 packages containing approximately equal portions of not less than 0.5 gram each, packaged in accordance with the requirements of § 146b.101 (b).

(iii) The polymyxin B used in making the batch: 5 packages containing approximately equal portions of not less than 0.5 gram each.

(iv) The neomycin used in making the batch: 5 packages containing approximately equal portions of not less than 0.5 gram each.

(v) In case of an initial request for certification, the ingredients used in making the batch: 1 package of each ointment-base ingredient, containing approximately 200 grams; 1 package of each suspending or dispersing agent used, containing approximately 5 grams; 1 package of each sulfonamide used, containing approximately 5 grams.

(4) The results referred to in subparagraph (2) (ii), (iii), and (iv) of this paragraph and the samples referred to in subparagraph (3) (ii), (iii), and (iv) of this paragraph are not required if such results or samples have been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i), (ii), (iii), (iv), and (v) of this section.

(2) If the Commissioner considers that investigations other than examination of such packages are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigation.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

PART 146C—CERTIFICATION OF CHLORTETRACYCLINE (OR TETRACYCLINE) AND CHLORTETRACYCLINE- (OR TETRACYCLINE-) CONTAINING DRUGS

Sec.
146c.201 Chlortetracycline hydrochloride.
146c.202 Chlortetracycline ointment (chlortetracycline hydrochloride ointment), chlortetracycline calcium ointment, chlortetracycline calcium cream; tetracycline hydrochloride ointment (tetracycline hydrochloride in oil suspension).
146c.203 Chlortetracycline troches; tetracycline hydrochloride troches.
146c.204 Chlortetracycline capsules; tetracycline hydrochloride capsules; tetracycline capsules.
146c.205 Chlortetracycline powder; tetracycline hydrochloride powder; tetracycline powder.
146c.206 Chlortetracycline ophthalmic; tetracycline hydrochloride ophthalmic.
146c.207 Chlortetracycline tablets; tetracycline tablets.
146c.208 Chlortetracycline otic; tetracycline hydrochloride otic.
146c.209 Chlortetracycline dental cones.
146c.210 Chlortetracycline dental paste.
146c.211 Chlortetracycline surgical powder; tetracycline hydrochloride surgical powder.
146c.212 Chlortetracycline suppositories; tetracycline hydrochloride suppositories.
146c.213 Chlortetracycline gauze packing.
Sec.
146c.214 Chlortetracycline dressing.
146c.215 Chlortetracycline with vasoconstrictor; chlortetracycline with -----.
146c.217 Chlortetracycline calcium oral drops; chlortetracycline calcium syrup; tetracycline syrup.
146c.218 Tetracycline hydrochloride.
146c.219 Crude chlortetracycline oral veterinary.
146c.220 Tetracycline.
146c.221 Tetracycline hydrochloride for intramuscular use.
146c.222 Tetracycline hydrochloride oral suspension; tetracycline calcium oral suspension.
146c.223 Chlortetracycline - neomycin-streptomycin - penicillin ointment; chlortetracycline-neomycin - dihydrostreptomycin-penicillin ointment; tetracycline hydrochloride - neomycin-streptomycin - penicillin ointment; tetracycline hydrochloride - neomycin - streptomycin-penicillin ointment.
146c.224 Tetracycline hydrochloride-nystatin capsules.
146c.225 Tetracycline hydrochloride-nystatin tablets.
146c.226 Tetracycline and vasoconstrictor suspension; tetracycline and ------ suspension.
146c.227 Chlortetracycline spray dressing.

AUTHORITY: §§ 146c.201 to 146c.227 issued under sec. 701, 52 Stat. 1055; 21 U. S. C. 371. Interpret or apply sec. 507, 59 Stat. 463, as amended; 21 U. S. C. 357.

§ 146c.201 *Chlortetracycline hydrochloride (chlortetracycline hydrochloride salt)*—(a) *Standards of identity, strength, quality, and purity.* Chlortetracycline hydrochloride is the yellow hydrochloride salt or crystalline hydrochloride salt of a kind of chlortetracycline or a mixture of two or more such salts with or without one or more suitable and harmless buffer substances if it is intended for intravenous use. It is so purified and dried that:

(1) Its potency, and the potency of the chlortetracycline used in the manufacture of chlortetracycline for intravenous use, is not less than 900 micrograms per milligram, except if it is intended for use solely in the manufacture of a veterinary drug for nonparenteral use its potency is not less than 820 micrograms per milligram;

(2) It is sterile;

(3) It is nontoxic;

(4) It is nonpyrogenic;

(5) It contains no histamine nor histamine-like substances;

(6) Its moisture content is not more than 2.0 percent;

(7) Its pH in an aqueous solution containing 10 milligrams per milliliter is not less than 2.3 and not more than 3.3, except if it is intended for intravenous use and it contains buffer substances its pH is not less than 8 and not more than 9.5.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is intended for intravenous use, it shall be packaged in immediate containers of colorless, transparent glass, closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness; each such container shall contain not more than 1.0 gram unless it is intended solely for veterinary use and is conspicuously so labeled, and each shall contain one or more suitable and harmless buffer substances, or each shall be packaged in combination with a container of a suitable and harmless diluent.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams in the immediate container;

(iii) The statement "Expiration date ------------," the blank being filled in with the date which is 12 months, or if it is crystalline chlortetracycline 36 months, after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) The statement "For manufacturing use," "For repacking," or "For manufacturing use or repacking," when packaged for repacking or for use as an ingredient in the manufacture of another drug, as the case may be; and

(v) If it is packaged for intravenous use and contains buffer substances, the name of each such substance used.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is intended solely for intravenous veterinary use, the statement "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian."

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing:

(i) If it is intended for use by man, adequate directions and warnings for its use by practitioners licensed by law to administer such drug.

(ii) If it is intended for intravenous veterinary use, adequate directions and warnings for its use by veterinarians licensed by law to administer such drug.

(iii) If it is intended solely for veterinary use other than for intravenous injection and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(iv) A statement of the conditions under which such solutions should be stored, including a reference to their instability when stored under other conditions, and a statement "Sterile solutions must be injected immediately after preparation."

(d) *Request for certification, check tests and assays; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of milligrams in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed; and if it is intended for intravenous use and contains buffer substances, the date and the results of the latest test for potency of the chlortetracycline used in making such batch. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, sterility, toxicity, pyrogens, histamine content, crystallinity (if it is the crystalline salt), moisture, and pH. If such batch or any part thereof is to be packaged with a solvent such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) If such batch is packaged for dispensing, such person shall submit with his request an accurately representative sample of the batch, consisting of the following:

(i) For all tests except sterility; 1 immediate container for each 5,000 immediate containers in such batch, but in no case less than 8 or more than 15 immediate containers.

(ii) For sterility testing; 10 immediate containers.

Such sample shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(3) If such batch is packaged for repacking or for use as an ingredient in the manufacture of another drug, such person shall submit with his request an accurately representative sample of the batch, consisting of the following:

(i) For all tests except sterility; 5 packages, each containing approximately 0.5 gram.

(ii) For sterility testing; 10 packages, each containing approximately 40 milligrams.

Each such package shall be packaged in accordance with the requirements of paragraph (b) of this section.

(4) In connection with contemplated requests for certification of repacked batches or batches of another drug in the manufacture of which it is to be used, the manufacturer of a batch which is to be so repacked or used may request the Commissioner to make check tests and assays on a sample of such batch, taken as prescribed by subparagraph (3) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(5) If such batch is intended for intravenous use and it contains buffer substances, such person shall submit in connection with his request (unless it has been previously submitted) one immediate container containing approximately 0.5 gram of the chlortetracycline used in making such batch.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $10.00 for each immediate container in the samples submitted in accordance with paragraph (d) (2) (i), (3) (i), and (4) of this section; $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) (5) of this section.

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146c.202 *Chlortetracycline ointment (chlortetracycline hydrochloride ointment), chlortetracycline calcium ointment, chlortetracycline calcium cream; tetracycline hydrochloride ointment (tetracycline hydrochloride in oil suspension)*—(a) *Standards of identity, strength, quality, and purity.* Chlortetracycline ointment is crystalline chlortetracycline hydrochloride or chlortetracycline calcium in a suitable and harmless ointment base. Tetracycline hydrochloride ointment is crystalline tetracycline hydrochloride in a suitable and harmless ointment base. It may contain a suitable local anesthetic, cortisone, hydrocortisone, or a suitable ester of cortisone or hydrocortisone, and one or more suitable and harmless preservatives. Its moisture content is not more than 1 percent if it is chlortetracycline hydrochloride or tetracycline hydrochloride ointment. Its potency is not less than 1 milligram per gram. The chlortetracycline hydrochloride used in making the chlortetracycline hydrochloride ointment and in preparing the chlortetracycline calcium used in making the chlortetracycline calcium ointment conforms to the requirements of § 146c.201 (a), except paragraph (a) (1), (2), (4), and (5) of that section, but its potency is not less than 750 micrograms per milligram. The tetracycline hydrochloride used conforms to the requirements of § 146c.218 (a), except paragraph (a) (2), (4), and (5) of that section. Each other ingredient used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* The ointment shall be packaged in collapsible tubes which are well-closed containers as defined by the U. S. P., or in containers of glass or plastic that are tight containers as defined by the U. S. P. Unless it is labeled solely for hospital use, each such container shall contain not more than 2 ounces, except if it is intended for ophthalmic use each such container shall contain not more than ⅛-ounce, if it is a collapsible tube, or more than ½-ounce if it is a tight container. Each such container shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practices shall be disregarded.

(c) *Labeling.* Each package of ointment shall bear on its label or labeling as hereinafter indicated:

(1) On the outside wrapper or container and the immediate container of the package:

(i) The batch mark;

(ii) The potency per gram, expressed in terms of its equivalency of chlortetracycline hydrochloride or as tetracycline hydrochloride;

(iii) If it contains preservatives, cortisone, hydrocortisone, or an ester of cortisone or hydrocortisone, or a local anesthetic, the name and quantity of each such substance;

(iv) The statement "Expiration date --------," the blank being filled in with the date which is 24 months, if it is chlortetracycline calcium ointment or tetracycline hydrochloride ointment, or 36 months, if it is chlortetracycline hydrochloride ointment, after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container, if it is packaged for ophthalmic use by man or if it contains cortisone, hydrocortisone, or an ester of cortisone or hydrocortisone, the statement "Caution: Federal law prohibits dispensing without prescription," and a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such ointment by practitioners licensed by law to administer such drug; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the label and labeling, if it contains one or more of the active ingredients specified in paragraph (a) of this section, after the name "chlortetracycline ointment," "chlortetracycline calcium ointment," "chlortetracycline calcium cream," or "tetracycline hydrochloride ointment," wherever it appears, the words "with ----------," in juxtaposition with such name, the blank being

filled in with the common or usual name of each such ingredient used.

(4) If it is not packaged for ophthalmic use by man or it does not contain cortisone, hydrocortisone, or an ester of cortisone or hydrocortisone, a circular or other labeling within or attached to the package bearing adequate directions and warnings for prophylactic use by man, or for the veterinary use of such ointment. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other uses of such ointment by practitioners licensed by law to administer such drug will be sent on request to such a practitioner.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of ointment shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the chlortetracycline or tetracycline hydrochloride used in making such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that each component of the ointment base used conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency and moisture.

(ii) The chlortetracycline or tetracycline hydrochloride used in making the batch; potency, toxicity, moisture, pH, crystallinity, and extinction coefficient, if it is tetracycline hydrochloride.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one package for each 5,000 packages in the batch, but in no case less than five packages or more than 12 packages, collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The chlortetracycline or tetracycline hydrochloride used in making the batch; ten packages, containing approximately equal portions of not less than 60 milligrams each, packaged in accordance with the requirements of § 146c.201 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch: 1 package of each component of the ointment base, each containing approximately 200 grams; 1 package of each preservative used, each containing approximately 5 grams; and if cortisone, hydrocortisone, or an ester of cortisone or hydrocortisone is used, 1 package of such ingredient, containing approximately 100 milligrams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of ointment under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i), (ii), and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations. The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146c.203 *Chlortetracycline troches (chlortetracycline hydrochloride troches); tetracycline hydrochloride troches*—(a) *Standards of identity, strength, quality, and purity.* Chlortetracycline troches and tetracycline hydrochloride troches are troches composed of crystalline chlortetracycline or crystalline tetracycline hydrochloride and one or more suitable and harmless diluents, binders, and lubricants, with or without one or more suitable and harmless preservatives, colorings, and flavorings. The potency of each troche is not less than 5 milligrams; the moisture content is not more than 2 percent. The chlortetracycline used conforms to the requirements of §146c.201 (a), except § 146c.201 (a) (1), (2), (4) and (5), but its potency is not less than 750 micrograms per milligram. The tetracycline hydrochloride used conforms to the requirements of § 146c.218 (a), except § 146c.218 (a) (2), (4) and (5). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each troche is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the troches by a plug of cotton or other like material. The composition of the immediate container, or foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of troches shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams in each troche of the batch;

(iii) If it contains a preservative, the name and quantity of each such ingredient; and

(iv) The statement "Expiration date ____________," the blank being filled in with the date which is 24 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 36 months or 48 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after being stored for such period of time such drug as prepared by him complies with the standards prescribed therefor by paragraph (a) of this section: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription."

(ii) If it is packaged for dispensing, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of troches shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the chlortetracycline or tetracycline hydrochloride used in making such batch was completed, the number of milligrams in each troche, the quantity of each ingredient used in making the batch, the date on which the latest assay of the troches comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per troche and average moisture.

(ii) The chlortetracycline or tetracycline hydrochloride used in making the batch; purity, toxicity, moisture, pH, crystallinity, and extinction coefficient if it is tetracycline hydrochloride.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one troche for each 5,000 troches in the batch, but in no case less than 20 troches or more than 100 troches, collected by taking single troches at such intervals throughout the entire time the troches are being made that the quantities made during the intervals are approximately equal.

(ii) The chlortetracycline or tetracycline hydrochloride used in making the batch; 10 packages, each containing approximately equal portions of not less than 60 milligrams, packaged in accordance with the requirements of § 146c.201 (b).

(iii) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of troches under the regulations in this part shall be:

(1) $1.00 for each troche in the sample submitted in accordance with paragraph (d) (3) (i) of this section, $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such troches, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146c.204 *Chlortetracycline capsules (chlortetracycline hydrochloride capsules); tetracycline hydrochloride capsules; tetracycline capsules*—(a) *Standards of identity, strength, quality, and purity.* Chlortetracycline capsules, tetracycline hydrochloride capsules, and tetracycline capsules are capsules composed of crystalline chlortetracycline, tetracycline hydrochloride, or tetracycline, with or without one or more suitable sulfonamides and with or without one or more suitable and harmless vitamin substances, buffer substances, vegetable oils, preservatives, diluents, binders, lubricants, colorings, and flavorings, enclosed in a gelatin capsule. Each capsule shall contain not less than 50 milligrams of chlortetracycyine, tetracycline hydrochloride, or tetracycline, unless it is intended solely for veterinary use and is conspicuously so labeled. Its moisture content is not more than 2 percent if it contains chlortetracycline and not more than 3 percent if it contains tetracycline hydrochloride or tetracycline. The chlortetracycline used conforms to the requirements of § 146c.201 (a), except § 146c.201 (a) (2), (4), and (5). The tetracycline hydrochloride used conforms to the requirements of § 146c.218 (a), except § 146c.201 (a) (2), (4), and (5). The tetracycline used conforms to the requirements of § 146c.220 (a). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each capsule is enclosed in a foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the capsules by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams in each capsule of the batch;

(iii) If it contains preservatives, sulfonamides, or vitamin substances, the name and quantity of each such ingredient;

(iv) The statement "Expiration date -------," the blank being filled in with the date that is 60 months after the month during which the batch was certified if it is chloretetracycline hydrochloride, or with the date that is 36 months after the month during which the batch was certified if it is tetracycline hydrochloride or tetracycline, or with the date that is 24 months after the month during which the batch was certified if it contains one or more vitamin substances: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) The statement: "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the label and labeling, if it contains one or more sulfonamides or vitamin substances, after the name "chlortetracycline capsules" or "tetracycline hydrochloride capsules" or "tetracycline capsules," wherever either such name appears, the words "with sulfonamide(s)" or "with vitamin ----" (the blank being filled in with the name of the vitamin ingredient used) or "with vitamins" (if it contains more than one vitamin ingredient), in juxtaposition with such name.

(4) On a circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the chlortetracycline, tetracycline hydrochloride, or tetracycline used in making such batch was completed, the number of milligrams in each capsule, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per capsule and average moisture.

(ii) The chlortetracycline, tetracycline hydrochloride, or tetracycline used in making the batch; potency, toxicity, moisture, pH, crystallinity, and extinction coefficient if it is chlortetracycline hydrochloride or tetracycline.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one capsule for each 5,000 capsules in the batch, but in no case less than 20 capsules or more than 100 capsules, collected by taking single capsules at such intervals throughout the entire time of preparation that the quantities encapsulated during the intervals are approximately equal.

(ii) The chlortetracyline, tetracycline hydrochloride, or tetracycline used in making the batch; ten packages, each containing approximately equal portions of not less than 60 milligrams, packaged in accordance with the requirements of § 146c.201 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $1.00 for each capsule in the sample submitted in accordance with paragraph (d) (3) (i) of this section, $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such capsules and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification, unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146c.205 *Chlortetracycline powder (chlortetracycline hydrochloride powder); tetracycline hydrochloride powder; tetracycline powder*—(a) *Standards of identity, strength, quality, and purity.* Chlortetracycline powder, tetracycline hydrochloride powder, and tetracycline powder are crystalline chlortetracycline hydrochloride, tetracycline hydrochloride, or tetracycline, with or without one or more suitable and harmless vitamin substances, and with or without suitable and harmless buffer substances, preservatives, diluents, colorings, flavorings, and local anesthetics (if it is intended for use solely as a dusting powder). The content of chlortetracycline or tetracycline hydrochloride or tetracycline is not less than 15 milligrams per gram of powder. The moisture content of chlortetracycline powder or tetracycline hydrochloride powder is not more than 2 percent. The moisture content of tetracycline powder is not more than 7.5 percent. The chlortetracycline used conforms to the requirements of § 146c.201 (a), except § 146c.201 (a) (2), (4), and (5). The tetracycline hydrochloride used conforms to the requirements of § 146c.218 (a), except subparagraphs (2), (4), and (5) of that paragraph. The tetracycline used conforms to the requirements of § 146c.220 (a). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P. The composition of the immediate container shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limits therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams of chlortetracycline or tetracycline hydrochloride or tetracycline (expressed in terms of equivalency of tetracycline hydrochloride) per gram; or, if it is intended for use solely as an ingredient in the drinking water of animals and is conspicuously so labeled, the number of grams of drug per pound in the immediate container;

(iii) The statement "Expiration date ________," the blank being filled in with the date that is 48 months after the month during which the batch was certified if it is chlortetracycline hydrochloride powder, or with the date that is 24 months after the month during which the batch was certified if it is tetracycline hydrochloride powder or tetracycline powder or if it contains one or more vitamin substances: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(iv) If it contains a preservative, a local anesthetic, or vitamin substances, the name and quantity of each such ingredient.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the label and labeling, if it contains one or more vitamin substances, after the name "chlortetracycline powder," "tetracycline hydrochloride powder," or "tetracycline powder," wherever such name appears, the words "with vitamin ___________" (the blank being filled in with the name of the vitamin ingredient used), or "with vitamins" (if it contains more than one vitamin ingredient), in juxtaposition with such name.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the chlortetracycline, tetracycline hydrochloride or tetracycline used in making such batch was completed, the number of milligrams in each immediate container, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency and moisture.

(ii) The chlortetracycline, tetracycline hydrochloride, or tetracycline used in making the batch; potency, toxicity, moisture, pH, crystallinity, and extinction coefficient if it is tetracycline hydrochloride or tetracycline.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 containers in the batch, but in no case less than 5 or more than 12 immediate containers, unless each such container is packaged to contain more than 1.0 gram, in which case the sample shall consist of 1.0 gram for each 5,000 immediate containers in the batch, but in no case less than five 1.0-gram portions or more than twelve 1.0-gram portions, except if it is intended for use as an ingredient in the drinking water of animals, each portion in the sample submitted shall consist of 1 ounce in lieu of 1.0 gram. Such sample shall be collected by taking single immediate containers, 1.0-gram portions, or 1-ounce portions at such intervals throughout the entire time the containers are being filled that the quantities filled during the intervals are approximately equal.

(ii) The chlortetracycline, tetracycline hydrochloride, or tetracycline used in making the batch; 10 packages, each containing approximately equal portions of not less than 60 milligrams, packaged in accordance with the requirements of § 146c.201 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (3) (i), (ii), and (iii) of this section.

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

(f) *Exemption of chlortetracycline powder for veterinary use, tetracycline hydrochloride powder for veterinary use, and tetracycline powder for veterinary use from certification.* Chlortetracycline powder, tetracycline hydrochloride powder, and tetracycline powder that conform to the requirements of paragraphs (a) (except that if they contain one or more added vitamin substances such substances are essential for nutritive purposes, and except that they may contain one or more added mineral substances essential for nutritive purposes), (b), and (c) of this section shall be exempt from the requirements of sections 502 (l) and 507 of the act, if they comply with all the following conditions:

(1) They are intended solely for veterinary use and are conspicuously so labeled.

(2) If they contain added vitamins or minerals, the labels bear the name and quantity of each such substance and a statement that such substances are present only for furnishing additional vitamins and minerals while animals are eating less feed.

(3) The labels bear an expiration date that is not more than 48 months, or 24 months if it contains a vitamin substance or it is tetracycline hydrochloride powder or tetracycline powder, after the month during which the batch was last assayed and released by the manufacturer.

(4) The labels bear a statement that solutions prepared with the drugs are stable for not more than 24 hours.

(5) The circular or other labeling within or attached to the package bears information that only the antibiotics are intended for the prevention or treatment of the following conditions, and further, bears directions and warnings adequate for such use:

(i) Pinkeye and superficial cuts and abrasions.

(ii) Bacterial enteritis in swine.

(iii) Bacterial pneumonia in swine.

(iv) Chronic respiratory disease (airsac infection), hexamitiasis, blue comb (mud fever, nonspecific infectious enteritis) in poultry.

(v) Infectious sinusitis in poultry.

§ 146c.206 *Chlortetracycline ophthalmic (chlortetracycline hydrochloride ophthalmic); tetracycline hydrochloride ophthalmic*—(a) *Standards of identity, strength, quality, and purity.* Chlortetracycline ophthalmic and tetracycline hydrochloride ophthalmic is crystalline chlortetracycline or crystalline tetracycline hydrochloride, with or without one or more suitable and harmless preservatives, buffer substances, and diluents. It is sterile. Its moisture content is not more than 5 percent. The chlortetracycline or tetracycline hydrochloride is of such quantity that when dissolved as directed the potency of such solution is not less than 1,000 micrograms per milliliter and maintains its labeled potency after it has been kept for 2 days at a temperature of 15° C. (59° F.). Such solution has a pH of 8.2, ± 0.2. The chlortetracycline used conforms to the requirements of § 146c.201 (a) except subparagraphs (2), (4), and (5) and the tetracycline hydrochloride used conforms to the requirements of § 146c.218 (a) except subparagraphs (2), (4), and (5). Each other buffer and diluent used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* The immediate container shall be a tight container as defined by the U. S. P.; its closure shall be one through which a hypodermic needle cannot be introduced; and the container shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each such container shall contain not less than 5 milligrams, and each may be packaged in combination with a container of the solvent, sterile distilled water U. S. P.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams in the immediate container;

(iii) The statement "Expiration date --------," the blank being filled in with the date which is 12 months if it is tetracycline hydrochloride opthalmic or 36 months if it is chlortetracycline ophthalmic after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the imediate container if such immediate container is packaged in an individual wrapper or container.

(iv) If it is packaged in combination with a container of a solvent, the statement "Warning—Not for injection;"

(v) If it contains preservatives, the name and quantity of each such substance.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless previously submitted) the date on which the latest assay of the chlortetracycline or tetracycline hydrochloride used in making such batch was completed, the number of milligrams in each immediate container, the quantity of each buffer and diluent used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each buffer and diluent used in making the batch conform to the requirements prescribed therefor, if any, by this section. If such batch or any part thereof is to be packaged with a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, moisture, and pH of the solution prepared as directed in its labeling.

(ii) The chlortetracycline or tetracycline hydrochloride used in making the batch; potency, toxicity, moisture, pH, crystallinity, and extinction coefficient, if it is tetracycline hydrochloride.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers or more than 12 immediate containers.

(*b*) For sterility testing; 10 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The chlortetracycline or tetracycline hydrochloride used in making the batch; ten packages, each containing approximately equal portions of not less than 60 milligrams packaged in accordance with the requirements of § 146c.201 (b).

(iii) In case of an initial request for certification, each buffer and diluent used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (3) (i) (*a*), (ii), and (iii) of this section.

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146c.207 *Chlortetracycline tablets (chlortetracycline hydrochloride tablets); tetracycline tablets (tetracycline hydrochloride tablets).* Chlortetracycline tablets and tetracycline tablets are tablets than conform to all requirements and are subject to all procedures prescribed by § 146c.204 for chlortetracycline capsules and tetracycline capsules, except that the average moisture content of the tablets is not more than 3.0 percent and its expiration date is not more than 48 months.

§ 146c.208 *Chlortetracycline otic (chlortetracycline hydrochloride otic, chlortetracycline hydrochloride for ear solution); tetracycline hydrochloride otic (tetracycline hydrochloride for ear solution)*—(a) *Standards of identity, strength, quality, and purity.* Chlortetracycline otic, tetracycline otic is a packaged combination of one immediate container of crystalline chlortetracycline or crystalline tetracycline hydrochloride and one immediate container of a suitable and harmless solution. The chlortetracycline or tetracycline hydrochloride is of such quantity that when dissolved as directed the potency of such solution is not less than 5 milligrams per milliliter after it has been kept for 7 days at a temparture of 15° C. (59° F.). The chlortetracycline used conforms to the requirements of § 146c.201 (a), except § 146c.201 (a) (2), (4), and (5). The tetracycline hydrochloride used conforms to the requirements of § 146c.218 (a) except § 146c.218 (a) (2), (4), and (5). Each substance used in the preparation of the solution contained in the packaged combination, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Each immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated the following:

(1) On the outside wrapper or container and on the immediate container of the chlortetracycline or tetracycline hydrochloride:

(i) The batch mark;

(ii) The number of milligrams in the immediate container;

(iii) The statement "Expiration date --------," the blank being filled in with the date which is 24 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such container is packaged in an individual wrapper or container;

(iv) The statement "Warning—Not for injection."

(2) On the outside wrapper or container and on the immediate container of the solution in the packaged combination:

(i) A statement giving the method of dissolving the chlortetracycline or tetracycline hydrochloride in the solution;

(ii) The potency per milliliter after the chlortetracycline or tetracycline hydrochloride has been dissolved therein; and

(iii) The conditions under which the solution should be stored, including a reference to its instability when stored under other conditions, and the statement "The solution may be kept in a refrigerator for 1 week without significant loss of potency."

(3) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the number of milligrams in each immediate container thereof, the date on which the latest assay of the batch was completed, the batch mark, and (unless it was previously submitted) the date on which the latest assay of the chlortetracycline or tetracycline hydrochloride used in making such batch was completed, the quantity of each ingredient used in making the solution included in the packaged combination, and a statement that such solution conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency and moisture.

(ii) The solution after the chlortetracycline or tetracycline hydrochloride has been disolved therein; potency.

(iii) The chlortetracycline or tetracycline hydrochloride used in making the batch; potency, toxicity, moisture, pH, crystallinity, and extinction coefficient if it is tetracycline hydrochloride.

(3) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one package for each 5,000 packages in the batch, but in no case less than 5 packages or more than 12 packages, collected by taking a single package at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The chlortetracycline or tetracycline hydrochloride used in making the batch; 10 packages, each containing approximately equal portions of not less than 60 milligrams, packaged in accordance with the requirements of § 146c.201 (b).

(iii) In case of an initial request for certification, or when any change is made in composition of such solution; 5 packages of the solution included in the combination.

(4) No result referred to in subparagraph (2) (iii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (3) (i), (ii), and (iii) of this section.

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigation. The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146c.209 *Chlortetracycline dental cones (chlortetracycline hydrochloride dental cones).* Chlortetracycline dental cones conform to all requirements prescribed by § 146c.203 for chlortetracycline troches, and are subject to all procedures prescribed by § 146c.203 for chlortetracycline troches, except that they may contain a suitable local anesthetic.

§ 146c.210 *Chlortetracycline dental paste (chlortetracycline hydrochloride dental paste).* Chlortetracycline dental paste conforms to all requirements prescribed by § 146c.202 for chlortetracycline ointment, and is subject to all procedures prescribed by § 146c.202 for chlortetracycline ointment, except that:

(a) Its potency is not less than 30 milligrams per gram.

(b) Its moisture content is not more than 3 percent.

(c) It contains one or more suitable and harmless binders, and it may contain one or more suitable and harmless colorings and flavorings.

(d) It is packaged in immediate containers of glass which meet the tests for tight containers as defined by the U. S. P.

§ 146c.211 *Chlortetracycline surgical powder (chlortetracycline hydrochloride surgical powder); tetracycline hydrochloride surgical powder*—(a) *Standards of identity, strength, quality, and purity.* Chlortetracycline surgical powder and tetracycline hydrochloride surgical powder are crystalline chlortetracycline or crystalline tetracycline hydrochloride, with or without suitable and harmless diluents, preservatives, and lubricants. The content of chlortetracycline or tetracycline hydrochloride is not less than 50 milligrams per gram of powder. It is sterile. Its moisture content is not more than 2 percent. The chlortetracycline used conforms to the requirements of § 146c.201 (a), except § 146c.201 (a) (4) and (5). The tetracycline hydrochloride used conforms to the requirements of § 146c.218 (a), except § 146c.218 (a) (4) and (5). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity thereof beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of surgical powder shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams of chlortetracycline or tetracycline hydrochloride per gram of powder in the immediate container;

(iii) The statement "Expiration date ____________," the blank being filled in with the date which is 24 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) If it contains a preservative, the name and quantity of each such ingredient.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the chlortetracycline or tetracycline hydrochloride used in making such batch was completed, the number of milligrams of chlortetracycline or tetracycline hydrochloride in each immediate container, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch and a statement that each such ingredient conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, moisture.

(ii) The chlortetracycline or tetracycline hydrochloride used in making the batch; potency, sterility, toxicity, moisture, pH, crystallinity, and extinction coefficient if it is tetracycline hydrochloride.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers or more than 12 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The chlortetracycline or tetracycline hydrochloride used in making the batch; ten packages, each containing approximately equal portions of not less than 60 milligrams, packaged in accordance with the requirements of § 146c.201 (b).

(iii) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (3) (i), (ii), and (iii) of this section.

(2) If the Commissioner considers that investigations other than examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146c.212 *Chlortetracycline suppositories (chlortetracycline hydrochloride suppositories); tetracycline hydrochloride suppositories*—(a) *Standards of identity, strength, quality, and purity.* Chlortetracycline suppositories and tetracycline hydrochloride suppositories are suppositories composed of crystalline chlortetracycline or tetracycline hydrochloride in a suitable and harmless base, with or without one or more suitable and harmless preservatives. The potency of each suppository is not less than 100 milligrams, except if it is intended for rectal use its potency is not less than 50 milligrams. Its moisture content is not more than 1 percent. The chlortetracycline used conforms to the requirements of § 146c.201 (a), except § 146c.201 (a) (1), (2), (4), and (5), but its potency is not less than 750 micrograms per milligram. The tetracycline hydrochloride used conforms to the requirements of § 146c.218 (a), except § 146c.218 (a) (2), (4), and (5). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P., and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of milligrams of chlortetracycline or tetracycline hydrochloride in each suppository of the batch.

(iii) If it contains a preservative, the name and quantity of each such ingredient.

(iv) The statement "Expiration date --------," the blank being filled in with the date which is 24 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the chlortetracycline or tetracycline hydrochloride used in making such batch was completed, the number of milligrams of chlortetracycline or tetracycline hydrochloride in each suppository, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch, and a statement that each such ingredient conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per suppository and moisture.

(ii) The chlortetracycline or tetracycline hydrochloride used in making the batch; potency, toxicity, moisture, pH, crystallinity, and extinction coefficient if it is tetracycline hydrochloride.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one suppository for each 5,000 suppositories in the batch, but in no case less than 20 or more than 100 suppositories, collected by taking single suppositories at such intervals throughout the entire time the suppositories are being made that the quantities made during the intervals are approximately equal.

(ii) The chlortetracycline or tetracycline hydrochloride used in making the batch; 10 packages, each containing approximately equal portions of not less than 60 milligrams, packaged in accordance with § 146c.201 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $1.00 for each suppository in the samples submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section.

(2) If the Commissioner considers that investigations other than examination of such packages are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146c.213 *Chlortetracycline gauze packing (chlortetracycline hydrochloride gauze packing)*—(a) *Standards of identity, strength, quality, and purity.* Chlortetracycline gauze packing is absorbent gauze that is impregnated with crystalline chlortetracycline. Its content of chlortetracycline is not less than 4 milligrams per gram and not less than 1.0 milligram per linear foot of gauze. It is sterile. Its moisture content is not more than 5 percent. The chlortetracycline used conforms to the standards prescribed therefor by § 146c.201 (a), except subparagraphs (2), (4), and (5) of that paragraph. The absorbent gauze used conforms to the standards prescribed therefor by the U. S. P.

(b) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P., shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of milligrams of chlortetracycline per gram and per linear foot of gauze.

(iii) The length, width, and type of gauze contained in the package.

(iv) The statement "Expiration date __________," the blank being filled in with the date which is 36 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the immediate container, the statement "Sterility cannot be guaranteed if the package bears evidence of damage or has been previously opened."

(3) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of chlortetracycline gauze packing shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the chlortetracycline used in making such batch was completed, the potency of each gram and of each linear foot of the gauze packing, the date on which the latest assay of the batch was completed, and a statement that the absorbent gauze used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per gram and per linear foot of the gauze packing, sterility, and average moisture.

(ii) The chlortetracycline used in making the batch; potency, toxicity, moisture, and pH.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility: one package for each 5,000 packages in the batch, but in no case less than 5 packages or more than 12 packages.

(*b*) For sterility testing: 10 packages. Such samples shall be collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The chlortetracycline used in making the batch; five packages, each containing approximately equal portions of not less than 60 milligrams, packaged in accordance with the requirements of § 146c.201 (b).

(iii) In case of an initial request for certification, one package consisting of approximately 5 linear yards, or the equivalent, of the absorbent gauze used.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i) (*a*), (ii), and (iii) of this section.

(2) If the Commissioner considers that investigations other than examination of such chlortetracycline gauze packing and packages are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations. The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146c.214 *Chlortetracycline dressing (chlortetracycline hydrochloride dressing)*—(a) *Standards of identity, strength, quality, and purity.* Chlortetracycline dressing is absorbent gauze impregnated with chlortetracycline ointment. Each square inch of such dressing shall contain not less than 2 milligrams of chlortetracycline. It is sterile. Its moisture content is not more than 5 percent. The chlortetracycline ointment used conforms to the standards prescribed for chlortetracycline ointment by § 146c.202 (a), except that its potency is not less than 20 milligrams per gram. The absorbent gauze used conforms to the standards prescribed therefor by the U. S. P.

(b) *Packaging.* In all cases the immediate container for each chlortetracycline dressing shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of grams of chlortetracycline ointment contained in each dressing and the number of milligrams of chlortetracycline per gram of ointment.

(iii) The length, width, and type of gauze contained in the dressing.

(iv) The statement "Expiration date __________," the blank being filled in with the date which is 24 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the immediate container, the statement "Sterility cannot be guaranteed if package bears evidence of damage or has been previously opened."

(3) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of chlortetracycline dressings shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the chlortetracycline used in making such batch was completed, the number of grams of chlortetracycline ointment contained in each dressing of the batch and its potency per gram, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency of chlortetracycline per dressing, sterility, and average moisture.

(ii) The chlortetracycline used in making the batch; potency, toxicity, moisture, and pH.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility; one dressing for each 5,000 dressings in the batch, but in no case less than 5 or more than 12 dressings.

(*b*) For sterility testing; 10 dressings. Such samples shall be collected by taking single dressings at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The chlortetracycline used in making the batch; five packages, each containing approximately equal portions of not less than 60 milligrams, packaged in accordance with the requirements of § 146c.201 (b).

(iii) In case of an initial request for certification, one package consisting of approximately five linear yards, or the equivalent, of the absorbent gauze used.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees*. The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (3) (i) (*a*), (ii), and (iii) of this section.

(2) If the Commissioner considers that investigations other than examination of such dressings and packages are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146c.215 *Chlortetracycline with vasoconstrictor (chlortetracycline hydrochloride with vasoconstrictor); chlortetracycline with ______ (chlortetracycline hydrochloride with ______) (the blank being filled in with the common or usual name of the vasoconstrictor)*—(a) *Standards of identity, strength, quality, and purity*. Chlortetracycline with vasoconstrictor is a dry mixture of crystalline chlortetracycline and a suitable vasoconstrictor, with or without suitable and harmless diluents, preservatives, colorings, and flavorings, or it is a packaged combination of one immediate container of crystalline chlortetracycline with or without suitable and harmless diluents, preservatives, colorings, and flavorings and one immediate container of a solution of a suitable vasoconstrictor. The chlortetracycline is of such quantity that when dissolved as directed the potency of such solution is not less than 1 milligram per milliliter and maintains its labeled potency after it has been kept for 4 days in a refrigerator. Such solution has a pH of not less than 2.75 and not more than 3.3. The moisture content of the dry mixture is not more than 5.0 percent. The chlortetracycline used conforms to the requirements of § 146c.201 (a), except subparagraphs (2), (4), and (5) of that paragraph. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging*. Each immediate container shall be a tight container as defined by the U. S. P., and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling*. Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and on the immediate container of the chlortetracycline:

(i) The batch mark.

(ii) The number of milligrams of chlortetracycline in such container.

(iii) The statement "Expiration date ________," the blank being filled in with the date which is 36 months after the month during which the batch was certified: *Provided, however*, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container and on the immediate container of the solution in the packaged combination, a statement giving the method of dissolving the chlortetracycline.

(3) On the outside wrapper or container and on the immediate container in which the finished drug is prepared for use:

(i) The potency per milliliter after the chlortetracycline has been dissolved therein.

(ii) The statement "Warning—Not for injection."

(iii) The conditions under which the solution should be stored, including a reference to its instability when stored under other conditions, and the statement: "The solution may be kept in a refrigerator for 4 days without significant loss of potency."

(4) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however*, That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(5) On a circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples*. (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of chlortetracycline with vasoconstrictor shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the number of milligrams of chlortetracycline in such immediate container, and (unless it was previously submitted) the date on which the latest assay of the chlortetracycline used in making such batch was completed, the quantity of each ingredient used in making the batch, the quantity of each ingredient used in making the solution included in the packaged combination, and a statement that such solution conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency and average moisture.

(ii) The chlortetracycline used in making the batch; potency, toxicity, moisture, pH, and crystallinity.

(3) Except as otherwise provided in subparagraph (4) of this paragraph,

such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers or more than 12 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The chlortetracycline used in making the batch; 10 packages, each containing approximately equal portions of not less than 60 milligrams, packaged in accordance with the requirements of § 146c.201 (b).

(iii) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately 5 grams.

(iv) In case of an initial request for certification of the packaged combination of chlortetracycline with vasoconstrictor, or when any change is made in the composition of such solution; five packages of the solution included in the combination.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container or package in the samples submitted in accordance with paragraph (d) (3) (i), (ii), (iii), and (iv) of this section.

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146c.217 *Chlortetracycline calcium oral drops; chlortetracycline calcium syrup; tetracycline syrup*—(a) *Standards of identity, strength, quality, and purity.* Chlortetracycline calcium oral drops, chlortetetracycline calcium syrup, and tetracycline syrup are chlortetracycline calcium prepared from crystalline chlortetracycline hydrochloride or crystalline tetracycline, with or without one or more suitable sulfonamides and one or more suitable and harmless buffer substances, suspending and stabilizing agents, and preservatives, suspended in a suitable and harmless vehicle. Each milliliter shall contain a quantity of chlortetracycline calcium or tetracycline equivalent to not less than 25 milligrams of chlortetracycline hydrochloride or tetracycline hydrochloride. It is nontoxic. The pH is not less than 6.5 nor more than 9.0, except if it is tetracycline syrup the pH is not less than 4.5 nor more than 5.5. The crystalline chlortetracycline hydrochloride used conforms to the requirements of § 146c.201 (a), except § 146c.201 (a) (2), (4), and (5). The crystalline tetracycline used conforms to the requirements of § 146c.220. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The potency per milliliter expressed in terms of its equivalency of chlortetracycline hydrochloride or tetracycline hydrochloride.

(iii) The name and quantity of each sulfonamide and preservative used in making the batch.

(iv) The statements "Warning—Not for injection" and "Shake well."

(v) The statement "Expiration date -----------," the blank being filled in with the date which is 12 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container, if it is intended for use by humans, the statement "Caution: Federal law prohibits dispensing without prescription" and a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer such drug; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the label and labeling, if it contains one or more sulfonamides, after the name "chlortetracycline calcium oral drops" or "chlortetracycline calcium syrup," or "tetracycline syrup," wherever it appears, the words "with sulfonamide(s)," in juxtaposition with such name.

(4) On a circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the chlortetracycline hydrochloride or tetracycline used in making such batch was completed, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch, and a statement that each such ingredient conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per milliliter, toxicity, pH.

(ii) The chlortetracycline hydrochloride or tetracycline used in making the batch; potency, toxicity, moisture, pH, crystallinity, and extinction coefficient if it is tetracycline.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one package for each 5,000 packages in the batch, but in no case less than 5 or more than 12 packages, collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The chlortetracycline hydrochloride or tetracycline used in making the batch; 10 packages each containing approximately equal portions of not less than 60 milligrams, packaged in accordance with the requirements of § 146c.201 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i), (ii), and (iii) of this section.

(2) If the Commissioner considers that investigations other than examina-

tion of such packages are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146c.218 *Tetracycline hydrochloride*—(a) *Standards of identity, strength, quality, and purity.* Tetracycline hydrochloride is the crystalline hydrochloride salt of the deschloro derivative of a kind of chlortetracycline or a mixture of two or more such salts, with or without one or more suitable and harmless stabilizing agents. It is so purified and dried that:

(1) Its potency, and the potency of the tetracycline hydrochloride used in the manufacture of tetracycline hydrochloride for intravenous use, is not less than 900 micrograms per milligram.

(2) It is sterile.

(3) It is nontoxic.

(4) It is nonpyrogenic.

(5) It contains no histamine nor histamine-like substance.

(6) Its moisture content is not more than 2 percent.

(7) Its pH in an aqueous solution containing 10 milligrams per milliliter is not less than 1.8 and not more than 2.8, except if it is intended for use by injection its pH is not less than 2.0 and not more than 3.0.

(8) Its extinction coefficient $E^{1\%}_{1\,\mathrm{cm.}}$, and the extinction coefficient of the tetracycline hydrochloride used in the manufacture of tetracycline for intravenous use, is 372±15 at 380 mμ.

(b) *Packaging; labeling; request for certification, check tests and assays, samples; fees.* Tetracycline hydrochloride conforms to all requirements and procedures prescribed for chlortetracycline hydrochloride by § 146c.201 (b), (c), (d), and (e), except that:

(1) It shall be labeled with an expiration date that is 24 months after the month during which the batch was certified.

(2) The person who requests certification of a batch of tetracycline hydrochloride that contains stabilizing agents and is intended for intravenous use shall submit with his request (unless they were previously submitted) the results of the latest tests and assays made on the batch of the tetracycline hydrochloride used in making such batch for potency and extinction coefficient and a sample consisting of two packages each containing approximately 500 milligrams of the tetracycline hydrochloride used in making such batch for potency and extinction coefficient.

(3) The fee for the services rendered with respect to each immediate container of the tetracycline hydrochloride used in the manufacture of a batch of tetracycline hydrochloride for intravenous use submitted in accordance with the requirements prescribed therefor by subparagraph (2) of this paragraph shall be $4.00.

§ 146c.219 *Crude chlortetracycline oral veterinary*—(a) *Standards of identity, strength, quality, and purity.* Crude chlortetracycline oral veterinary is crude chlortetracycline with suitable and harmless diluents, buffer substances, and suspending or dispersing agents. It contains not less than 10 grams of chlortetracycline activity per pound. Its moisture content is not more than 6 percent.

(b) *Packaging.* In all cases the immediate container shall be a well-closed container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each such container shall contain not more than 100 pounds.

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of grams of chlortetracycline in each pound of the batch.

(iii) The statement "For oral veterinary use only."

(iv) The statement "Expiration date ______," the blank being filled in with the date which is 12 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the circular or other labeling within or attached to the package, adequate directions and warnings for the use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the number of grams of chlortetracycline in each pound of the batch, and the quantity of each other ingredient used in making the batch, and the date on which the latest assay of the batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for average potency and average moisture.

(2) Such person shall submit in connection with his request a sample of the batch consisting of 1 ounce for each 3,000 pounds in the batch, but in no case less than five 1-ounce portions or more than twelve 1-ounce portions collected by taking single 1-ounce portions at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) (2) of this section.

(2) If the Commissioner considers that investigations other than examination of such drug are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations. The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

(f) *Exemption of crude chlortetracycline oral veterinary from certification.* Crude chlortetracycline oral veterinary that conforms to the requirements of paragraphs (a) (except that it may contain one or more essential vitamin and mineral substances for nutritive purposes), (b), and (c) of this section shall be exempt from the requirements of sections 502 (l) and 507 of the act, if it complies with all the following conditions:

(1) If it contains added vitamins or minerals, its label bears the name and quantity of each such substance and a statement that such substances are present only for furnishing additional vitamins and minerals while animals are eating less feed.

(2) The label bears an expiration date that is not more than 12 months after the month during which the batch was last assayed and released by the manufacturer.

(3) The label bears a statement that solutions prepared with the drug are stable for not more than 24 hours.

(4) The circular or other labeling within or attached to the package bears information that only the antibiotic is intended for the prevention or treatment of the following conditions, and further, bears directions and warnings adequate for such use:

(i) Bacterial enteritis in swine.

(ii) Bacterial pneumonia in swine.

(iii) Chronic respiratory disease (air-sac infection), hexamitiasis, blue comb (mud fever, nonspecific infectious enteritis) in poultry.

(iv) Infectious sinusitis in poultry.

§ 146c.220 *Tetracycline*—(a) *Standards of identity, strength, quality, and purity.* Tetracycline is the hydrated or anhydrous crystalline compound of the deschloro derivative of a kind of chlortetracycline, or a mixture of two or more such compounds. It is so purified that:

(1) Its potency is not less than 975 micrograms per milligram on the anhydrous basis.

(2) It is nontoxic.

(3) Its moisture content is not more than 13 percent.

(4) Its pH in an aqueous suspension prepared by adding 10 milligrams per

milliliter is not less than 3.0 and not more than 7.0.

(5) Its extinction coefficient $E\frac{1\%}{1\text{ cm.}}$ is 402±15 at 380 $m\mu$ calculated on the anhydrous basis.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limits therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of tetracycline shall bear on its outside wrapper or container and the immediate container, as hereinafter indicated, the following:

(1) The batch mark.

(2) The number of micrograms of tetracycline per milligram expressed in terms of its equivalency of tetracycline hydrochloride, and the total number of grams in the immediate container.

(3) The statement "Expiration date --------------," the blank being filled in with the date which is 24 months after the month during which it was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(4) The statement "For use only in the manufacture of nonparenteral drugs."

(5) The statement "Caution: Federal law prohibits dispensing without prescription."

(d) *Request for certification, check tests and assays; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, toxicity, moisture, pH, crystallinity, and extinction coefficient.

(2) Such person shall submit with his request an accurately representative sample of the batch consisting of 10 packages, each containing approximately 60 milligrams taken from a different part of such batch and each packaged in accordance with the requirements of paragraph (b) of this section.

(3) In connection with contemplated requests for certification of batches of another drug in the manufacture of which tetracycline is to be used, the manufacturer of the batch that is to be so used may request the Commissioner to make check tests and assays on a sample of such batch taken as prescribed by subparagraph (2) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer the results of such check tests and assays as are so requested.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (2) and (3) of this section.

(2) If the Commissioner considers that investigations other than examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146c.221 *Tetracycline hydrochloride for intramuscular use*—(a) *Standards of identity, strength, quality, and purity.* Tetracycline hydrochloride for intramuscular use is a dry mixture of tetracycline hydrochloride, magnesium chloride, and one or more suitable buffer substances, with or without one or more suitable preservatives and anesthetic agents. It is sterile. It is nonpyrogenic. Its moisture content is not more than 5 percent. Its pH in an aqueous solution containing 10 milligrams per milliliter is not less than 2.0 and not more than 3.0. The tetracycline hydrochloride used conforms to the requirements of § 146c.218 (a). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The immediate containers shall be of colorless transparent glass, closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness. Each such container shall contain not less than 100 milligrams of tetracycline hydrochloride, and each may be packaged in combination with a container of a suitable and harmless diluent.

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of milligrams of tetracycline hydrochloride in the immediate container.

(iii) The name and quantity of each other ingredient in the immediate container.

(iv) The statement "Expiration date --------," the blank being filled in with the date that is 24 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(v) The statement "For intramuscular use only."

(2) On the outside wrapper or container, the statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing:

(i) If it is intended for use by man, adequate directions and warnings for its use by practitioners licensed by law to administer such drug.

(ii) If it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(iii) A statement of the conditions under which solutions prepared from the drug should be stored and the statement "Sterile solutions may be stored at room temperature for 24 hours without significant loss of potency."

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the tetracycline hydrochloride used in making such batch was completed, the number of milligrams of tetracycline hydrochloride in each package, the date on which the latest assay of the drug comprising the batch was completed, the quantity of each other ingredient used in making the batch, and a statement that each such ingredient conforms to the requirements prescribed therefor by this section. If such batch or any part thereof is to be packaged with a diluent, such request shall also be accompanied by a statement that such diluent conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (5) of this paragraph, such person shall submit in connection with his request the results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch: Potency, sterility, pyrogens, moisture, pH.

(ii) The tetracycline hydrochloride used in making the batch: Potency, toxicity, histamine, extinction coefficient, and crystallinity.

(3) Except as otherwise provided by subparagraph (5) of this paragraph, if such batch is packaged for dispensing, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility: 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 10 or more than 17 immediate containers.

(*b*) For sterility testing: 10 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The tetracycline hydrochloride used in making the batch: 10 packages containing approximately equal portions of not less than 250 milligrams, packaged in accordance with the requirements of § 146c.201 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch: 1 package of each, containing approximately 5 grams.

(iv) In case of an initial request for the certification of a batch which is to be packaged in combination with a diluent that is not recognized by the U. S. P. or when any change is made in the composition of such diluent: 5 packages of the diluent included in the combination.

(4) If such batch is packaged for repacking, such person shall submit with his request a sample consisting of the following:

(i) For all tests except sterility: 10 packages, each containing approximately 0.25 gram.

(ii) For sterility testing: 10 packages, each containing approximately 40 milligrams of tetracycline hydrochloride.

Each such package shall be packaged in accordance with the requirements of paragraph (b) of this section.

(5) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (3) (i) (*a*), (ii), (iii), (iv), and (4) (i) of this section.

(2) If the Commissioner considers that investigations other than examination of such packages are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146c.222 *Tetracycline hydrochloride oral suspension; tetracycline hydrochloride oral solution; tetracycline calcium oral suspension*—(a) *Standards of identity, strength, quality, and purity.* Tetracycline hydrochloride oral suspension, tetracycline hydrochloride oral solution, and tetracycline calcium oral suspension are tetracycline hydrochloride or tetracycline calcium prepared from tetracycline hydrochloride, with one or more suitable and harmless suspending and dispersing agents (unless it is tetracycline hydrochloride oral solution); with or without one or more suitable sulfonamides; and with or without one or more suitable and harmless colorings, flavorings, buffer substances, and preservatives, suspended or dissolved in a suitable and harmless vehicle. If it is tetracycline hydrochloride oral suspension it may contain one or more suitable and harmless vitamin substances. Each milliliter shall contain not less than the equivalent of 25 milligrams of tetracycline hydrochloride. Its moisture content is not more than 2 percent if it is tetracyline hydrochloride oral suspension and not more than 7 percent if it is tetracycline hydrochloride oral solution. Its pH is not less than 2.0 and not more than 3.5 if it is tetracycline hydrochloride oral solution and not less than 7.0 and not more than 8.0 if it is tetracycline calcium oral suspension. The tetracycline hydrochloride used conforms to the standards prescribed by § 146c.218 (a), except § 146c.218 (a) (2), (4), and (5). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* The immediate container shall be a tight container as defined by the U. S. P., and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The potency per milliliter expressed in milligrams of tetracycline hydrochloride or its equivalency of tetracycline hydrochloride.

(iii) The statement "Shake well."

(iv) The name and quantity of each sulfonamide, preservative, and vitamin substance used in making the batch.

(v) The statement "Expiration date ------------," the blank being filled in with the date that is 12 months (if it contains one or more vitamin substances or if it is tetracycline hydrochloride oral solution) or 18 months (if it is tetracycline hydrochloride oral suspension or tetracycline calcium oral suspension) after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the label and labeling:

(i) If it is tetracycline hydrochloride oral suspension and it contains one or more vitamin substances or sulfonamides, after the name "tetracycline hydrochloride oral suspension," wherever it appears, the words "with sulfonamide(s)" or "with vitamin ----------," the blank being filled in with the name of the vitamin ingredient used, or "with vitamins," if it contains more than one vitamin ingredient, in juxtaposition with such name.

(ii) If it is tetracycline hydrochloride oral solution or tetracycline calcium oral suspension and it contains one or more sulfonamides, after the name "tetracycline hydrochloride oral solution" or "tetracycline calcium oral suspension," wherever it appears, the words "with sulfonamide(s)," in juxtaposition with such name.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the tetracycline hydrochloride used in making such batch was completed, the potency per milliliter of the batch, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch, and a statement that each such ingredient conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, each person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch: Average potency per milliliter, average moisture if it is tetracycline hydrochloride oral suspension or tetracycline hydrochloride oral solution, and pH if it is tetracycline hydrochloride oral solution or tetracycline calcium oral suspension.

(ii) The tetracycline hydrochloride used in making the batch: Potency, toxicity, moisture, pH, crystallinity, and extinction coefficient.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch: 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 or more than 12 immediate containers, collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The tetracycline hydrochloride used in making the batch: 10 packages, each containing approximately equal portions of not less than 60 milligrams, packaged in accordance with the requirements of § 146c.201 (b).

(iii) In the case of an initial request for certification, each other ingredient used in making the batch: 1 package of each containing approximately 5.0 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i), (ii), and (iii) of this section.

(2) If the Commissioner considers that investigations other than the examination of such packages are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146c.223 *Chlortetracycline - neomycin-streptomycin-penicillin ointment; chlortetracycline - neomycin - dihydrostreptomycin - penicillin ointment; tetracycline hydrochloride - neomycin-streptomycin-penicillin ointment; tetracycline hydrochloride - neomycin-dihydrostreptomycin - penicillin ointment.* (a) Chlortetracycline-neomycin-streptomycin-penicillin ointment, chlortetracycline-neomycin-dihydrostreptomycin-penicillin ointment, tetracycline hydrochloride-neomycin-streptomycin-penicillin ointment, and tetracycline hydrochloride - neomycin - dihydrostreptomycin-penicillin ointment conform to all requirements and are subject to all procedures prescribed by § 146c.202 for chlortetraycycline hydrochloride ointment and tetracycline hydrochloride ointment, except that:

(1) They contain not less than 28 milligrams of chlortetracycline hydrochloride or tetracycline hydrochloride per gram.

(2) They contain not less than 14 milligrams of neomycin per gram. The neomycin used conforms to the requirements prescribed by § 146e.410 (a) (2) of this chapter.

(3) They contain not less than 14 milligrams of streptomycin or dihydrostreptomycin per gram. The streptomycin used conforms to the standards prescribed by § 146b.101 (a) of this chapter, except § 146b.101 (a) (2), (4), and (5). The dihydrostreptomycin used conforms to the standards prescribed by § 146b.103 of this chapter, except the standards for sterility, pyrogens, and histamine.

(4) They contain not less than 28,000 units of procaine penicillin G per gram. The procaine penicillin used conforms to the requirements prescribed by § 146a.44 (a) of this chapter, except § 146a.44 (a) (2) and (3).

(b) In lieu of the directions for labeling prescribed for chlortetracycline hydrochloride ointment and tetracycline hydrochloride ointment by § 146c.202 (c) (1) (ii) and (iii), each package shall bear on the outside wrapper or container and the immediate container the number of milligrams of chlortetracycline hydrochloride or tetracycline hydrochloride, neomycin, and streptomycin or dihydrostreptomycin per gram, and the number of units of procaine penicillin per gram. Its expiration date shall be 18 months after the month during which the batch was certified.

(c) In addition to complying with the requirements of § 146c.202 (d), a person who requests certification of a batch shall submit with his request a statement showing the batch marks and (unless they were previously submitted) the results and dates of the latest tests and assays of the neomycin, streptomycin or dihydrostreptomycin, and penicillin used in making the batch for potency, toxicity, moisture, pH, streptomycin content of the dihydrostreptomycin, crystallinity if it is crystalline dihydrostreptomycin, and crystillinity and penicillin G content of the procaine penicillin G. He shall also submit in connection with his request a sample consisting of not less than 8 packages of such ointment and (unless they were previously submitted), accurately representative samples of the following, in the quantities indicated.

(1) The neomycin used in making the batch: 5 packages, each containing approximately equal portions of not less than 0.5 gram.

(2) The streptomycin or dihydrostreptomycin used in making the batch: 5 packages, each containing approximately equal portions of not less than 0.5 gram.

(3) The procaine penicillin G used in making the batch: 10 packages, each containing approximately equal portions of not less than 300 milligrams.

(d) The fee for the services rendered with respect to each immediate container in the samples of neomycin, streptomycin or dihydrostreptomycin, and penicillin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146c.224 *Tetracycline hydrochloride-nystatin capsules.* Tetracycline hydrochloride-nystatin capsules are capsules that conform to all the requirements and procedures prescribed by § 146c.204 for tetracycline hydrochloride capsules, except that:

(a) Each capsule contains not less than 100,000 units of nystatin. The nystatin used is produced by the growth of Streptomyces noursei. It is a white to yellow to light-tan powder. It is very slightly soluble in water, moderately soluble in methanol, butanol, or propanol. Its potency is not less than 2,000 units per milligram. It is nontoxic. Its pH in a 3-percent aqueous suspension is not less than 7.5 and not more than 8.0. Its moisture content is not more than 5 percent. It exhibits absorption maxima at 291, 305, and 319 mμ when dissolved in methanol, and its specific rotation in dimethyl formamide at 20° C. is not more than ±25°.

(b) In addition to the labeling prescribed for tetracycline hydrochloride capsules, each package shall bear on its label or labeling the number of units of nystatin in each capsule of the batch.

(c) In addition to complying with the requirements of § 146c.204 (d), a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless they were previously submitted) the results and the date of the latest tests and assays of the nystatin used in making the batch for potency, toxicity, pH, moisture, and specific rotation. He shall also submit in connection with his request a sample consisting of not less than 30 capsules and (unless it was previously submitted) a sample consisting of 10 packages, each containing approximately equal portions of not less than 300 milligrams of the nystatin used in making the batch.

(d) The fee for the services rendered with respect to each container in the sample of nystatin submitted in accordance with the requirements prescribed therefor by paragraph (c) of this section shall be $4.00.

§ 146c.225 *Tetracycline hydrochloride-nystatin tablets.* Tetracycline hydrochloride-nystatin tablets are tablets that conform to all requirements and are subject to all procedures prescribed by § 146c.224 for tetracycline hydrochloride-nystatin capsules except that the expiration date is the date that is 24 months after the month during which the batch was certified.

§ 146c.226 *Tetracycline and vasoconstrictor suspension; tetracycline and ________ (the blank being filled in with the common or usual name of the vasoconstrictor) suspension*—(a) *Standards of identity, strength, quality, and purity.* Tetracycline and vasoconstrictor suspension is tetracycline and a suitable vasoconstrictor, with or without one or more suitable and harmless suspending or dispersing agents, preservatives, buffer substances, colorings, and flavorings, with or without cortisone or a suitable derivative of cortisone, suspended in a suitable and harmless vehicle. Each milliliter contains a quantity of tetracycline equivalent to not less than 3.75 milligrams of tetracycline hydrochloride. The pH is not less than 3.0 nor more than 5.0. The tetracycline used conforms to the requirements of § 146c.220 (a). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P., and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The potency per milliliter expressed in terms of its equivalency of tetracycline hydrochloride.

(iii) If the batch contains, in addition to tetracycline, one or more other active ingredients specified in paragraph (a) of this section, the name and quantity of each such other ingredient in each milliliter of the batch.

(iv) The statement "Expiration date ____________," the blank being filled in with the date that is 12 months after the month during which the batch was certified. *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(v) The statements "Warning—Not for injection" and "Shake well."

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the label or labeling, if it contains, in addition to tetracycline, one or more other active ingredients specified in paragraph (a) of this section, after the name "Tetracycline and vasoconstrictor suspension," wherever such name appears, the words "with ________," in juxtaposition with such name, the blank being filled in with the common or usual name of each such other ingredient used.

(4) On a circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the tetracycline used in making the batch was completed, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch, and a statement that each such ingredient conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch: Average potency per milliliter, and pH.

(ii) The tetracycline used in making the batch: Potency, toxicity, moisture, pH, crystallinity, and extinction coefficient.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch: One package for each 5,000 packages in the batch, but in no case less than 5 or more than 12 packages, collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The tetracycline used in making the batch: 10 packages, each containing approximately equal portions of not less than 60 milligrams, packaged in accordance with the requirements of § 146c.220 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch: One package of each containing approximately 5 grams, except if cortisone, or a derivative of cortisone is used, such package shall contain approximately 100 milligrams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i), (ii), and (iii) of this section.

(2) If the Commissioner considers that investigations other than examination of such packages are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146c.227 *Chlortetracycline spray dressing (chlortetracycline hydrochloride spray dressing)*—(a) *Standards of identity, strength, quality, and purity.* Chlortetracycline spray dressing is chlortetracycline hydrochloride ointment and one or more suitable and harmless inert gases. It is sterile. The chlortetracycline hydrochloride ointment used conforms to the standards prescribed for chlortetracycline hydrochloride ointment by § 146c.202 (a), except that its potency is not less than 20 milligrams per gram. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each such container shall contain not less than 30 grams of ointment and shall contain one or more suitable and harmless inert gases.

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of milligrams of chlortetracycline per gram of the chlortetracycline ointment and the number of grams of chlortetracyline ointment that shall be ejected when used as directed in the labeling.

(iii) The statement "Expiration date ________," the blank being filled in with the date that is 24 months after the month during which the batch was certified: *Provided, however*, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information and a statement that such brochure or other printed matter will be sent on request: *Provided, however*, That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the chlortetracycline used in making the batch was completed, the quantity of each ingredient used in making such batch, the date on which the latest assay of the drug comprising such batch was completed, and that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch: Average potency per gram, sterility, and moisture.

(ii) The chlortetracycline used in making the batch: Potency, toxicity, moisture, pH, and crystallinity.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility: 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 or more than 12 immediate containers.

(*b*) For sterility testing: 10 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The chlortetracycline used in making the batch: 5 packages, each containing approximately equal portions of not less than 60 milligrams, packaged in accordance with the requirements of § 146c.201 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch: 1 package of each component of the ointment base, each containing approximately 200 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $5.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i) (*a*), (ii), and (iii) of this section.

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

PART 146d—CERTIFICATION OF CHLORAMPHENICOL AND CHLORAMPHENICOL-CONTAINING DRUGS

Sec.

146d.301 Chloramphenicol.
146d.302 Chloramphenicol capsules.
146d.303 Chloramphenicol ointment.
146d.304 Chloramphenicol ophthalmic.
146d.305 Chloramphenicol palmitate.
146d.306 Chloramphenicol palmitate oral suspension.
146d.307 Chloramphenicol solution; chloramphenicol for aqueous injection.
146d.308 Chloramphenicol otic; chloramphenicol topical.
146d.309 Chloramphenicol - streptomycin capsules; chloramphenicol-dihydrostreptomycin capsules.
146d.310 Chloramphenicol tablets.
146d.311 Chloramphenicol palmitate-streptomycin oral suspension; chloramphenicol palmitate-dihydrostreptomycin oral suspension.

AUTHORITY: §§ 146d.301 to 146d.311 issued under sec. 701, 52 Stat. 1055; 21 U. S. C. 371. Interpret or apply sec. 507, 59 Stat. 463, as amended; 21 U. S. C. 357.

§ 146d.301 *Chloramphenicol* — (a) *Standards of identity, strength, quality, and purity.* Chloramphenicol is a white to grayish-white or yellowish-white crystalline powder, occurring as needles or elongated plates. It is neutral, slightly soluble in water, but freely soluble in alcohol. It has the chemical formula D-(—)-*threo*-1-*p* - nitrophenyl - 2 - dichloracetamido-1,3-propanediol. It is so purified and dried that:

(1) Its potency is not less than 900 micrograms per milligram;

(2) It is sterile;

(3) It is nontoxic;

(4) It is nonpyrogenic;

(5) It contains no histamine nor histamine-like substances;

(6) Its pH in saturated aqueous solution is not less than 4.5 and not more than 7.5;

(7) Its specific rotation in absolute ethanol at 20° C. is +20°±1.5°, and at 25° C. is +18.5°±1.5°;

(8) Its melting point is 151° C. ±2°;

(9) Its extinction coefficient $E_{1\,\mathrm{cm}}^{1\%}$ is 298±9 at 278 mμ when measured in aqueous solution.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing, it shall be in immediate containers of colorless transparent glass, closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness; each such container shall contain not more than 1.0 gm., and each may be packaged in combination with a suitable and harmless diluent.

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of grams in the immediate container;

(iii) The statement "Expiration date ____________," the blank being filled in with the date which is 60 months after the month during which the batch was certified: *Provided, however*, That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) The statement "For manufacturing use," "For repacking," or "For manufacturing use or repacking," when packaged for repacking or for use as an ingredient in the manufacture of another drug, as the case may be.

(2) On the outside wrapper or container, the statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for

veterinary use and is conspicuously so labeled.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing:

(i) If it is intended for use by man, adequate directions and warnings for its use by practitioners licensed by law to administer such drug.

(ii) If it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification, check tests and assays; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of chloramphenicol shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of grams in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, sterility, toxicity, pyrogens, histamine, pH, specific rotation, melting point, and extinction coefficient. If such batch or any part thereof is to be packaged with a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) If such batch is packaged for dispensing, such person shall submit with his request a sample consisting of one immediate container for each 5,000 immediate containers in such batch, but in no case shall such sample consist of less than 8 immediate containers or more than 15 immediate containers.

(3) If such batch is packaged for repacking or for use as an ingredient in the manufacture of another drug, such person shall submit with his request a sample containing ten approximately equal portions of at least 300 milligrams each, taken from different parts of such batch; each such portion shall be packaged in a separate container, and in accordance with the requirements of paragraph (b) of this section.

(4) In connection with contemplated requests for certification of repacked batches of chloramphenicol or batches of another drug in the manufacture of which it is to be used, the manufacturer of a batch which is to be so repacked or used may request the Commissioner to make check tests and assays on a sample of such batch, taken as prescribed by subparagraph (3) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $10.00 for each immediate container in the sample submitted in accordance with paragraph (d) (2), (3), and (4) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146d.302 *Chloramphenicol capsules*—(a) *Standards of identity, strength, quality, and purity.* Chloramphenicol capsules are capsules composed of chloramphenicol, with or without the addition of one or more suitable and harmless diluents, lubricants, colorings, and flavorings. The potency of each capsule is not less than 50 milligrams. The chloramphenicol used conforms to the requirements of § 146d.301 (a), except § 146d.301 (a) (2), (4), (5), and (6). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each chloramphenicol capsule is enclosed in a foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of chloramphenicol capsules shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams in each capsule of the batch; and

(iii) The statement "Expiration date ------------," the blank being filled in with the date which is 60 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of chloramphenicol capsules shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the chloramphenicol used in making such batch was completed, the number of milligrams in each capsule, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per capsule.

(ii) The chloramphenicol used in making the batch; potency, toxicity, specific rotation, melting point, and extinction coefficient.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one capsule for each 5,000 capsules in the batch, but in no case less than 20 capsules or more than 100 capsules, collected by taking single capsules at such intervals throughout the entire time of preparation that the quantities encapsulated during the intervals are approximately equal.

(ii) The chloramphenicol used in making the batch; ten packages, each containing approximately equal portions of not less than 300 milligrams each, packaged in accordance with the requirements of § 146d.301 (b).

(iii) In case of an initial request for certification, each diluent, lubricant, coloring, and flavoring used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of chloramphenicol capsules under the regulations in this part shall be:

(1) $1.00 for each capsule in the sample submitted in accordance with paragraph (d) (3) (i) of this section, $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such capsules and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146d.303 *Chloramphenicol ointment (chloramphenicol cream)*—(a) *Standards of identity, strength, quality, and purity.* Chloramphenicol ointment is chloramphenicol in a suitable and harmless ointment base, with or without suitable and harmless buffer substances, dispersing and suspending agents. It may contain cortisone or a suitable derivative of cortisone. If such base is water-miscible, it shall contain a suitable and harmless preservative. Its potency is not less than 1.0 milligram per gram. The chloramphenicol used conforms to the requirements of § 146d.301 (a), except subparagraphs (2), (4), and (5), of that paragraph. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless it is packaged in a single dose container, chloramphenicol ointment shall be packaged in collapsible tubes, which shall be well-closed containers as defined by the U. S. P., and shall not be larger than the ⅛-ounce size if such ointment is represented for ophthalmic use, and in no case larger than the 2-ounce size, except that if it is labeled solely for hospital use it may be packaged in immediate containers of glass which meet the test for tight containers as defined by the U. S. P. The composition of the immediate container and closure shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of chloramphenicol ointment shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams of chloramphenicol per gram of the batch or in each single-dose container;

(iii) If it contains cortisone or a derivative of cortisone, or preservatives, the name and quantity of each such ingredient; and

(iv) The statement "Expiration date --------," the blank being filled in with the date that is 60 months, or 24 months if it is packaged in immediate containers other than tin or glass, or 12 months if the ointment base is water-miscible, after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(4) On the label and labeling, if it contains one of the active ingredients specified in paragraph (a) of this section, after the name "chloramphenicol ointment," wherever it appears, the name of the active ingredient, in juxtaposition with such name.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of chloramphenicol ointment shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the chloramphenicol used in making such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that each component of the ointment base used conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per gram.

(ii) The chloramphenicol used in making the batch; potency, toxicity, pH, specific rotation, melting point, and extinction coefficient.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; 1 package for each 5,000 packages in the batch, but in no case less than 5 packages or more than 12 packages if it is packaged in immediate containers of tin or glass, and not less than 20 immediate containers or more than 100 immediate containers if it is packaged in immediate containers other than tin or glass, collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The chloramphenicol used in making the batch; 10 packages, each containing approximately equal portions of not less than 300 milligrams, packaged in accordance with the requirements of § 146d.301 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 200 grams, except if cortisone or a derivative of cortisone is used, such package shall contain approximately 100 milligrams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each multiple-dose package or $1.00 for each single-dose container in the sample submitted in accordance with paragraph (d) (3) (i) of this section, and $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations other than examination of such packages are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance

of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146d.304 *Chloramphenicol ophthalmic*—(a) *Standards of identity, strength, quality, and purity.* Chloramphenicol ophthalmic is chloramphenicol, with or without one or more suitable and harmless preservatives, buffer substances, and diluents. It may contain cortisone hydrocortisone, or a suitable ester of cortisone or hydrocortisone. It is sterile. The chloramphenicol is of such quantity that when prepared as directed in its labeling the potency of such solution or suspension is not less than 1.0 milligram per milliliter and maintains its labeled potency after it has been kept for 10 days at room temperature. Such solution or suspension has a pH of 7.3±0.2. The chloramphenicol used conforms to the requirements of § 146d.301 (a), except subparagraphs (2), (4), and (5) of that paragraph. Each other ingredient used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* The immediate container of chloramphenicol ophthalmic shall be a tight container as defined by the U. S. P. Its closure shall be one through which a hypodermic needle cannot be introduced. The composition of the immediate container and closure shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each such container may be packaged in combination with a container of the solvent, sterile distilled water U. S. P.

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of milligrams of chloramphenicol in the immediate container;

(iii) The statement "Expiration date ------," the blank being filled in with the date which is 60 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) If it is packaged in combination with a container of a solvent the statement "Warning—Not for injection;"

(v) If it contains cortisone, hydrocortisone, or an ester of cortisone or hydrocortisone, or preservatives, the name and quantity of each such substance.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(4) On the label and labeling, if it contains one of the active ingredients specified in paragraph (a) of this section, after the name "chloramphenicol ophthalmic," wherever it appears, the name of the ingredient in juxtaposition with such name.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of chloramphenicol ophthalmic shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless previously submitted) the date on which the latest assay of the chloramphenicol used in making such batch was completed, the number of milligrams of chloramphenicol in each immediate container, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each other ingredient used in making the batch, and a statement that each such ingredient conforms to the requirements prescribed therefor by this section. If such batch or any part thereof is to be packaged with a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, and pH of the solution or suspension prepared as directed in its labeling.

(ii) The chloramphenicol used in making the batch; potency, toxicity, pH, specific rotation, melting point, and extinction coefficient.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers or more than 12 immediate containers.

(*b*) For sterility testing; 10 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The chloramphenicol used in making the batch; 10 packages, each containing approximately equal portions of not less than 300 milligrams, packaged in accordance with the requirements of § 146d.301 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing aproximately 5.0 grams, except if cortisone acetate is used, such package shall contain approximately 100 milligrams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container or package in the samples submitted in accordance with paragraph (d) (3) (i) (*a*), (ii), and (iii) of this section.

(2) If the Commissioner considers that investigations other than examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification, unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146d.305 *Chloramphenicol palmitate*—(a) *Standards of identity, strength, quality, and purity.* Chloramphenicol palmitate is the white to grayish-white, tasteless, crystalline palmitic acid ester of chloramphenicol. It is so purified and dried that:

(1) It contains not less than 555 micrograms of chloramphenicol per milligram.

(2) It is nontoxic.

(3) Its melting point is 89°±3° C.

(4) Its extinction coefficient $E^{1\%}_{1\,\mathrm{cm}}$ is 178±6 at 271 mμ when measured in absolute ethanol.

The chloramphenicol used conforms to the requirements of § 146d.301 (a), except subparagraphs (2), (4), and (5) of that paragraph.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of chloramphenicol palmitate shall bear on its outside wrapper or container and the immediate container, as hereinafter indicated, the following:

(1) The batch mark.

(2) The number of grams in the immediate container and the number of milligrams of chloramphenicol per gram.

(3) The statement "Expiration date ____________," the blank being filled in with the date which is 48 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(4) The statement "For manufacturing use only."

(5) The statement "Caution: Federal law prohibits dispensing without prescription."

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of chloramphenicol palmitate shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch and (unless it was previously submitted) the date on which the latest assay of the drug comprising such batch was completed. Such request shall be accompanied or followed by results of tests and assays made by him on the batch for potency, toxicity, melting point, and extinction coefficient.

(2) Such person shall submit with his request a sample containing 10 approximately equal portions of at least 300 milligrams, each taken from different parts of such batch; each such portion shall be packaged in a separate container and in accordance with the requirements of paragraph (b) of this section.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container submitted in accordance with paragraph (d) (2) of this section.

(2) If the Commissioner considers that investigations other than examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146d.306 *Chloramphenicol palmitate oral suspension—*(a) *Standards of identity, strength, quality, and purity.* Chloramphenicol palmitate oral suspension is chloramphenicol palmitate and one or more suitable and harmless buffer substances, suspending agents, preservatives, colorings, and flavorings, with or without one or more suitable and harmless vitamin substances, suspended in a suitable and harmless vehicle. It contains not less than 30 milligrams of chloramphenicol per milliliter. Its pH is not less than 4.5 and not more than 7.0. The chloramphenicol palmitate used conforms to the requirements of § 146d.305 (a). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of chloramphenicol palmitate oral suspension shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of milligrams of chloramphenicol per milliliter.

(iii) The name and quantity of each preservative, and if it contains vitamin substances, the name and quantity of each such ingredient used in making the batch.

(iv) The statement "Expiration date ________," the blank being filled in with the date which is 48 months after the month during which the batch was certified, or with the date that is 24 months after the month during which the batch was certified if it contains one or more vitamin substances: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(4) On the label and labeling, if it contains one or more vitamin substances, after the name "chloramphenicol palmitate oral suspension," wherever it appears, the words "with vitamin ______" (the blank being filled in with the name of the vitamin ingredient used) or "with vitamins" (if it contains more than one vitamin ingredient), in juxtaposition with such name.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark, and (unless it was previously submitted) the date on which the latest assay of the chloramphenicol palmitate used in making such batch was completed, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each ingredient used in making the batch, and a statement that each such ingredient conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per milliliter, pH.

(ii) The chloramphenicol palmitate used in making the batch; potency, toxicity, melting point, extinction coefficient.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one package for each 5,000 packages in the batch, but in no case less than 5 or more than 12 packages, collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The chloramphenicol palmitate used in making the batch; 10 packages, each containing approximately equal portions of not less than 300 milligrams, packaged in accordance with the requirements of § 146d.305 (b).

(iii) In the case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i), (ii), and (iii) of this section.

(2) If the Commissioner considers that investigations other than examination of such packages are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146d.307 *Chloramphenicol solution; chloramphenicol for aqueous injection*—(a) *Standards of identity, strength, quality, and purity.* Chloramphenicol solution is chloramphenicol, with or without one or more suitable and harmless buffer substances, dissolved in one or more suitable and harmless solvents. Chloramphenicol for aqueous injection is a dry mixture of chloramphenicol and one or more suitable and harmless suspending or dispersing agents, buffer substances, and preservatives. It is so purified that:

(1) If it is the solution of the drug, its potency is 250 milligrams per milliliter.

(2) It is sterile.

(3) It is nontoxic.

(4) It is nonpyrogenic.

(5) It contains no histamine nor histamine-like substances.

(6) If it is chloramphenicol solution, its pH is not less than 4.7 and not more than 5.0. If it is the dry mixture of the drug, the pH of a suspension prepared as directed in its labeling is not less than 4.5 and not more than 7.5.

The chloramphenicol used conforms to the requirements of § 146d.301 (a). Each other ingredient used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate container shall be a tight container as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing and it is the solution of the drug, it shall be in hermetically sealed, colorless, transparent glass ampuls, each of which shall contain 2.0 milliliters. If it is packaged for dispensing and it is the dry mixture of the drug, it shall be in colorless, transparent glass containers, closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness, and each such container shall contain 1.0 gram or 2.0 grams of chloramphenicol.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) If it is the solution of the drug, the number of milligrams of chloramphenicol in each milliliter of the batch; and if it is the dry mixture of the drug, the number of grams of chloramphenicol in each immediate container.

(iii) The statement "Expiration date ________," the blank being filled in with the date which is 12 months after the month during which the batch was certified if it is the solution of the drug, or 48 months after the month during which the batch was certified if it is the dry mixture of the drug: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(iv) If it is the solution of the drug, the name of each solvent used; and if it is the dry mixture of the drug, the name and quantity of each preservative used.

(v) If it is the dry mixture of the drug, the statement "For intramuscular use only."

(2) On the outside wrapper or container, the statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing:

(i) If it is intended for use by man, adequate directions and warnings for its use by practitioners licensed by law to administer such drug.

(ii) If it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages in the batch, the number of milligrams or grams in each of such packages, the date on which the latest assay of the drug comprising the batch was completed, the batch mark and (unless it was previously submitted) the date on which the latest assay of the chloramphenicol used in making such batch was completed, the quantity of each ingredient used in making the batch, and a statement that each such ingredient conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, toxicity, pyrogens, histamine content, and pH.

(ii) The chloramphenicol used in making the batch; potency, specific rotation, melting point, and extinction coefficient.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility; one immediate container for each 5,000 immediate containers in such batch, but in no case less than 8 or more than 15 immediate containers.

(*b*) For sterility testing; 10 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The chloramphenicol used in making the batch; two immediate containers containing approximately 300 milligrams each, packaged in accordance with the requirements of § 146d.301 (b).

(iii) In case of an initial request for certification, each ingredient (unless it is recognized by the U. S. P. or N. F.) used in making the batch; one package of each, containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $10.00 for each immediate container in the sample submitted in accordance with paragraph (d) (3) (i) (*a*) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section.

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146d.308 *Chloramphenicol otic; chloramphenicol topical*—(a) *Standards of identity, strength, quality, and purity.* Chloramphenicol otic and chloramphenicol topical is chloramphenicol, with or without ethyl aminobenzoate, in a suitable and harmless vehicle. The potency of the solution is not less than 5 milligrams per milliliter. Its moisture content is not more than 2 percent. Its pH is not less than 4 and not more than 8. The chloramphenicol used conforms to the requirements of § 146d.301 (a), except subparagraphs (2), (4), and (5) of that paragraph. Each other ingredient used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Each immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of milligrams of chloramphenicol, and if it contains ethyl aminobenzoate, the quantity of such ingredient in each milliliter of the batch.

(iii) The statement "Expiration date ____________," the blank being filled in with the date which is 12 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(iv) The statement "Warning—For external use only."

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch the batch mark, and (unless it was previously submitted) the date on which the latest assay of the chloramphenicol used in making the batch was completed, the number of milligrams of chloramphenicol in each milliliter of the batch, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each other ingredient used in making the batch, and a statement that each such ingredient conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, moisture, and pH.

(ii) The chloramphenicol used in making the batch; potency, toxicity, pH, specific rotation, melting point, and extinction co-efficient.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 20 immediate containers or more than 100 immediate containers, collected by taking single immediate containers, before or after labeling, at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The chloramphenicol used in making the batch; 10 packages, each containing approximately equal portions of not less than 300 milligrams, packaged in accordance with the requirements of § 146d.301 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 5.0 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $1.00 for each immediate container in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section.

(2) If the Commissioner considers that investigations other than examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification, unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146d.309 *Chloramphenicol-streptomycin capsules; chloramphenicol-dihydrostreptomycin capsules.* (a) Chloramphenicol-streptomycin capsules and chloramphenicol - dihydrostreptomycin capsules conform to all requirements prescribed by § 146d.302 for chloramphenicol capsules, and are subject to all procedures prescribed by § 146d.302 for chloramphenicol capsules, except that:

(1) Each capsule contains not less than 125 milligrams of chloramphenicol.

(2) Each capsule contains not less than 125 milligrams of streptomycin or dihydrostreptomycin. The streptomycin used conforms to the standard prescribed therefor by § 146b.101 (a) of this chapter, except subparagraphs (2) and (4) of that paragraph. The dihydrostreptomycin used conforms to the standards prescribed therefor by § 146b.103 of this chapter, except the standards for sterility and pyrogens.

(3) Its moisture content is not more than 5 percent.

(4) In lieu of the labeling prescribed for chloramphenicol capsules by § 146d.302 (c) (1) (ii) and (iii), each package shall bear on the outside wrapper or container and the immediate container the number of milligrams of chloramphenicol and the number of milligrams of streptomycin or dihydrostreptomycin in each capsule of the batch and the statement "Expiration date ______," the blank being filled in with the date which is 24 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(5) In addition to complying with the requirements of § 146d.302 (d), a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the streptomycin or dihydrostreptomycin used in making the batch

for potency, toxicity, histamine content, moisture, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin sulfate. He shall also submit in connection with his request a sample consisting of not less than 30 capsules of such batch and (unless it was previously submitted) a sample consisting of 5 packages each containing approximately equal portions of not less than 500 milligrams of the streptomycin or dihydrostreptomycin used in making the batch, packaged in accordance with the requirements of § 146b.101 (b) of this chapter.

(b) The fee for the services rendered with respect to each immediate container in the sample of streptomycin or dihydrostreptomycin submitted in accordance with the requirements prescribed therefor by this section shall be $10.00.

§ 146d.310 *Chloramphenicol tablets.* Chloramphenicol tablets are tablets that conform to all requirements and are subject to all procedures prescribed by § 146d.302 for chloramphenicol capsules, except that the expiration date of such tablets shall be 24 months after the month during which the batch was certified.

§ 146d.311 *Chloramphenicol palmitate-streptomycin oral suspension; chloramphenicol palmitate-dihydrostreptomycin oral suspension.* Chloramphenicol palmitate-streptomycin oral suspension and chloramphenicol palmitate-dihydrostreptomycin oral suspension conform to all requirements and are subject to all procedures prescribed by § 146d.306 for chloramphenicol palmitate oral suspension, except that:

(a) It contains not less than 30 milligrams of streptomycin or dihydrostreptomycin per milliliter. The streptomycin used conforms to the standards prescribed by § 146b.101 (a) of this chapter, except § 146b.101 (a) (2), (4), and (6). The dihydrostreptomycin used conforms to the standards prescribed therefor by § 146b.103 of this chapter, except the standards for sterility, pyrogens, and moisture.

(b) In lieu of the directions for labeling prescribed by § 146d.306 (c) (1) (ii) and (iv), each package shall bear on the outside wrapper or container and the immediate container the number of milligrams of chloramphenicol and the number of milligrams of streptomycin or dihydrostreptomycin per milliliter, and its expiration date shall be 24 months after the month during which the batch was certified.

(c) In addition to complying with the requirements of § 146d.306 (d), a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless they were previously submitted) the results and date of the latest tests and assays of the streptomycin or dihydrostreptomycin used in making the batch for potency, toxicity, histamine content, pH, streptomycin content if it is dihydrostreptomycin, and crystallinity if it is crystalline dihydrostreptomycin. He shall also submit in connection with his request a sample consisting of not less than 6 packages of the batch and (unless it was previously submitted) a sample consisting of not less than 5 packages containing approximately equal portions of not less than 0.5 gram each of the streptomycin or dihydrostreptomycin used in making the batch, packaged in accordance with the requirements of § 146b.101 (b) of this chapter.

(d) The fee for the services rendered with respect to each immediate container in the sample of streptomycin or dihydrostreptomycin submitted in accordance with the requirements prescribed therefor by this section shall be $10.00.

PART 146e—CERTIFICATION OF BACITRACIN AND BACITRACIN-CONTAINING DRUGS

Sec.
146e.401 Bacitracin.
146e.402 Bacitracin ointment; zinc bacitracin ointment.
146e.403 Bacitracin tablets; zinc bacitracin tablets; bacitracin suppositories; zinc bacitracin suppositories; bacitracin implantation pellets; zinc bacitracin implantation pellets.
146e.404 Bacitracin troches; zinc bacitracin troches.
146e.405 Bacitracin with vasoconstrictor; bacitracin with -----.
146e.406 Bacitracin-tyrothricin troches; zinc bacitracin-tyrothricin troches.
146e.407 Bacitracin-tyrothicin ointment.
146e.408 Bacitracin ophthalmic.
146e.409 Bacitracin-polymyxin ointment.
146e.410 Bacitracin-neomycin tablets; zinc bacitracin neomycin tablets.
146e.411 Bacitracin-neomycin ointment; zinc bacitracin-neomycin ointment.
146e.412 Bacitracin-polymyxin tablets.
146e.413 Bacitracin-neomycin troches; zinc bacitracin-neomycin troches.
146e.414 Bacitracin-neomycin with vasocontrictor; bacitracin-neomycin with -----.
146e.415 Bacitracin-polymyxin troches; zinc bacitracin-polymyxin troches.
146e.416 Bacitracin methylene disalicylate.
146e.417 Powder bacitracin methylene disalicylate and streptomycin sulfate oral veterinary.
146e.418 Zinc bacitracin.
146e.419 Bacitracin - neomycin - polymyxin troches; zinc bacitracin-neomycin polymyxin troches.
146e.420 Bacitracin - tyrothricin - neomycin troches; zinc bacitracin-tyrothricin-neomycin troches.
146e.421 Bacitracin - neomycin - polymyxin tablets.
146e.422 Bacitracin - polymyxin - neomycin ointment.
146e.423 Soluble bacitracin methylene disalicylate.
146e.424 Bacitracin - neomycin - polymyxin with vasoconstrictor; bacitracin-neomycin-polymyxin with -----.
146e.425 Bacitracin powder.
146e.426 Tablets bacitracin methylene disalicylate and streptomycin sulfate oral veterinary.

AUTHORITY: §§ 146e.401 to 146e.426 issued under sec. 701, 52 Stat. 1055; 21 U. S. C. 371. Interpret or apply sec. 507, 59 Stat. 463, as amended; 21 U. S. C. 357.

§ 146e.401 *Bacitracin*—(a) *Standards of identity, strength, quality, and purity.* Bacitracin is a white to brown, neutral water-soluble polypeptide. It is so purified and dried that:

(1) Its potency is not less than 40 units per milligram, except that if it is packaged for dispensing and it is intended for systemic medication its potency is not less than 50 units per milligram;

(2) It is sterile;

(3) It is nontoxic;

(4) It is nonpyrogenic;

(5) Its moisture content is not more than 5 percent;

(6) Its pH in aqueous solution of 10,000 units per milliliter is not less than 5.5 and not more than 7.5.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P., shall be sterile at the time of filling and closing, shall be so sealed that the contents cannot be used without destroying the seal, and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. In case it is packaged for dispensing, it shall be in immediate containers of colorless transparent glass, closed by a substance through which a hypodermic needle may be introduced and withdrawn without removing the closure or destroying its effectiveness; each such container shall contain not more than 60,000 units (unless it is intended solely for veterinary use and is conspicuously so labeled) and may be packaged in combination with a container of the solvent, water for injection U. S. P., physiological salt solution U. S. P., or with a container of an aqueous solution of a suitable local anesthetic.

(c) *Labeling.* Each package shall bear on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in the immediate container;

(iii) If it is intended for systemic medication, the statement "For intramuscular use only";

(iv) The statement "Expiration date ____________," the blank being filled in with the date which is 18 months after the month during which the batch was certified, except if it is packaged for dispensing and it is intended for systemic medication the blank shall be filled in with the date which is 24 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(v) The statement "For manufacturing use," "For repacking," or "For manufacturing use or repacking," as the case may be, when packaged for repacking or for use as an ingredient in the manufacture of another drug.

(2) On the outside wrapper or container:

(i) If it is intended for use by man, the statement "Caution: Federal law prohibits dispensing without prescription."

(ii) If it is intended solely for veterinary use, and is conspicuously so labeled, the statement "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian."

(iii) If it is packaged for dispensing and it is intended for systematic medication the statement "Store in refrigerator not above 15° C. (59° F.)" or "Store below 15° C. (59° F.)."

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing, adequate directions and warnings for its use by practitioners licensed by law to administer such drug; the conditions under which such solutions should be stored, including a reference to their instability when stored under other conditions; and the statement "Sterile solution may be kept in refrigerator for 1 week without significant loss of potency."

(d) *Request for certification, check tests and assays; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of bacitracin shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of units in each package, and (unless it was previously submitted) the date on which the latest assay of the drug comprising the batch was completed. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, sterility, toxicity, pyrogens, moisture, and pH. If such batch or any part thereof is to be packaged with a solvent such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) If such batch is packaged for dispensing, such person shall submit with his request an accurately representative sample of the batch, consisting of the following:

(i) For all tests except sterility; one immediate container for each 5,000 immediate containers in such batch, but in no case less than 6 or more than 13 immediate containers, except if the total potency contained in such immediate containers is less than 100,000 units and a sample of such batch has not been previously submitted under subparagraph (3) or (4) of this paragraph, such person shall submit, in addition to the quantity specified herein, one other container which contains a quantity sufficient to make the total potency of all containers in the sample equal to approximately 100,000 units.

(ii) For sterility testing; 10 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(3) If such batch is packaged for repacking or for use as an ingredient in the manufacture of another drug, such person shall submit with his request an accurately representative sample of the batch, consisting of the following:

(i) For all tests except sterility; 6 packages.

(ii) For sterility testing; 10 packages. Each such package shall contain approximately 0.5 gram, taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(4) In connection with contemplated requests for certification of repacked batches or batches of another drug in the manufacture of which it is to be used, the manufacturer of a batch which is to be so repacked or used may request the Commissioner to make check tests and assays on a sample of such batch, taken as prescribed by subparagraph (3) of this paragraph. From the information required by subparagraph (1) of this paragraph may be omitted results of tests and assays not required for the batch when used in such other drug. The Commissioner shall report to such manufacturer results of such check tests and assays as are so requested.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (2) (i), (3) (i), and (4) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such immediate containers, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146e.402 *Bacitracin ointment; zinc bacitracin ointment*—(a) *Standards of identity, strength, quality, and purity.* Bacitracin ointment and zinc bacitracin ointment are composed of bacitracin or zinc bacitracin in a suitable and harmless ointment base, or they are a powder composed of bacitracin or zinc bacitracin and one or more suitable and harmless diluents, dispersing agents, and preservatives which, upon the addition of the quantity of water recommended in its labeling, produces an ointment. It may contain a suitable local anesthetic, cortisone, or a suitable derivative of cortisone, one or more suitable sulfonamides, and, if it is intended solely for veterinary use and is conspicuously so labeled, one or more suitable antifungal agents or rotenone. Its potency is not less than 500 units per gram. Its moisture content is not more than 1 percent, except if it is a powder its moisture content is not more than 5 percent. The zinc bacitracin used conforms to the requirements of § 146e.418 (a). The bacitracin used conforms to the requirements of § 146e.401 (a), except § 146e.401 (a) (1), (2) and (4), but its potency is not less than 30 units per milligram. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* If it is bacitracin or zinc bacitracin in an ointment base it shall be packaged in collapsible tubes, which shall be well-closed containers as defined by the U. S. P., and which shall not be larger than the 2-ounce size, except if it is labeled solely for hospital use; but in no case shall such ointment be packaged in containers other than collapsible tubes if it is labeled for ophthalmic use, and such tubes shall not be larger than the ⅛-ounce size. If it is a powder, it shall be packaged in immediate containers of glass which meet the tests for tight containers as defined by the U. S. P. The composition of the immediate container and closure shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units per gram of the batch, or if it is a powder, the number of units per gram after the addition of the quantity of water recommended in its labeling;

(iii) If the batch contains, in addition to bacitracin or zinc bacitracin, one or more other active ingredients specified in paragraph (a) of this section, the name and quantity of each such other ingredient per gram of the batch;

(iv) The statement "Expiration date --------," the blank being filled in with the date which is not more than 36 months after the month during which the batch was certified, except if it is zinc bacitracin ointment the blank is filled in with the date that is 24 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(v) If it is a powder, the statement "After the addition of water the ointment may be stored in refrigerator for 1 week without significant loss of potency."

(2) On the outside wrapper or container, if it is packaged for ophthalmic use by humans or if it is intended for use by humans and it contains cortisone or a derivative of cortisone or one or more sulfonamides, the statement "Caution: Federal law prohibits dispensing without prescription" and a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such ointment by practitioners licensed by law to administer such drug; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the outside wrapper or container, if it is intended solely for veterinary use and it contains fludrocortisone (9 α-fluorohydrocortisone), the statement "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian" and a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such ointment by practitioners licensed by law to administer such drug; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or printed matter will be sent on request: *Provided, however*, That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(4) On the label or labeling, if it contains, in addition to bacitracin or zinc bacitracin, one or more other active ingredients specified in paragraph (a) of this section, after the name "bacitracin ointment" or "zinc bacitracin ointment," wherever such name appears, the words "with ________," in juxtaposition with such name, the blank being filled in with the common or usual name of each such other ingredient used.

(5) On a circular or other labeling within or attached to the package, unless it is packaged for ophthalmic use in humans or is intended for human use and contains cortisone or a derivative of cortisone or one or more sulfonamides, or if it is intended for veterinary use and it contains fludrocortisone (9 α-fluorohydrocortisone), adequate directions and warnings for prophylactic use in humans or for the veterinary use of such ointment. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other uses of such ointment by practitioners licensed by law to administer such drug will be sent to such practitioners upon request.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall sumbit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the bacitracin or zinc bacitracin used in making such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and that each component of the ointment base used conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency and moisture.

(ii) The bacitracin or zinc bacitracin used in making the batch; potency, toxicity, moisture, pH, and zinc content, if it is zinc bacitracin.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one package for each 5,000 packages in the batch, but in no case less than 5 packages or more than 12 packages, collected by taking single packages at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The bacitracin used in making the batch; six packages, each containing approximately equal portions of not less than 500 milligrams, packaged in accordance with the requirements of § 146e.401 (b).

(iii) The zinc bacitracin used in making the batch; 5 packages, each containing approximately equal portions of not less than 1.0 gram, packaged in accordance with the requirements of § 146e.418 (b).

(iv) In case of an initial request for certification, each other ingredient used in making the batch; one package of each containing approximately 200 grams, except if cortisone or a derivative of cortisone is used, such package shall contain approximately 100 milligrams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) or (iii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (i), (ii), (iii), and (iv) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

(f) *Exemption of bacitracin ointment from certification.* Bacitracin ointment that conforms to the requirements of paragraphs (a), (b), and (c) of this section, except paragraph (c) (1) (iv) of this section, shall be exempt (unless it is the powder preparation described in paragraph (a) or it contains an antifungal agent, rotenone, cortisone or a derivative of cortisone) from the requirements of sections 502 (l) and 507 of the act, if it complies with the following conditions:

(1) The outside wrapper or container and the immediate container bear an expiration date not more than 36 months after the month during which the batch was last assayed and released by the manufacturer; and

(2) It is intended for use by man and is packaged for ophthalmic use, or it contains one or more sulfonamides and the brochure, printed matter, and circular referred to in paragraph (c) (2) of this section bear information for use of the drug only in the local treatment of those superficial infections caused by bacitracin-sensitive organisms; and further, that such brochure, printed matter, and circular bear directions and warnings adequate for such use by practitioners licensed by law to administer such drug; or

(3) It is intended for use by man and it is not packaged for ophthalmic use nor contains one or more sulfonamides, or it is intended solely for veterinary use and is conspicuously so labeled; and its labeling bears information that the drug is for use only in the prevention of infection in minor cuts and abrasions and, further, bears directions adequate for such use by the laity and a statement that use of the drug should be discontinued and a physician (if it is for human use) or a veterinarian (if it is for veterinary use) consulted if signs of infection or irritation appear.

§ 146e.403 *Bacitracin tablets; zinc bacitracin tablets; bacitracin suppositories; zinc bacitracin suppositories (if they are represented for vaginal use); bacitracin implantation pellets; zinc bacitracin implantation pellets (if they are represented for use by implanting under the skin of animals)*—(a) *Standards of identity, strength, quality, and purity.* Bacitracin tablets and zinc bacitracin tablets are tablets composed of bacitracin or zinc bacitracin, with or without the addition of one or more suitable and harmless buffer substances, diluents, binders, lubricants, colorings, and flavorings. The potency of each tablet is not less than 1,000 units nor more than 10,000 units. Its moisture content is not more than 5 percent. Unless it is represented to be used for inhalation therapy, the bacitracin used conforms to the requirements of § 146e.401 (a), except subparagraphs (1), (2), and (4) of that paragraph, but in no case is its potency less than 30 units per milligram. If it is represented to be used for inhalation therapy, the bacitracin used conforms to the requirements of § 146e.401 (a), except subparagraphs (2) and (4) of that paragraph. The zinc bacitracin used conforms to the requirements of § 146e.418 (a). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each tablet is enclosed in a foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the tablets by a plug of cotton or other like material. The composition of the immediate container, or of the foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in each tablet of the batch;

(iii) The statement "Expiration date ------------," the blank being filled in with the date which is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 18 months or 24 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(iv) If it is implantation pellets, the statement "For veterinary use only."

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure of other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the bacitracin or zinc bacitracin used in making such batch was completed, the number of units in each tablet, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor, if any, by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per tablet and average moisture.

(ii) The bacitracin or zinc bacitracin used in making the batch; potency, toxicity, moisture, pH, and zinc content, if it is zinc bacitracin.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one tablet for each 5,000 tablets in the batch, but in no case less than 20 tablets or more than 100 tablets, collected by taking single tablets at such intervals throughout the entire time of tableting that the quantities tableted during the intervals are approximately equal.

(ii) The bacitracin used in making the batch; six packages, each containing approximately equal portions of not less than 500 milligrams each, packaged in accordance with the requirements of § 146e.401 (b).

(iii) The zinc bacitracin used in making the batch; 5 packages, each containing approximately equal portions of not less than 1.0 gram, packaged in accordance with the requirements of § 146e.418 (b).

(iv) In case of an initial request for certification, each other substance used in making the batch; 1 package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) or (iii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $1.00 for each tablet in the sample submitted in accordance with paragraph (d) (3) (i) of this section, $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii), (iii) and (iv) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such tablets and packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146e.404 *Bacitracin troches; zinc bacitracin troches*—(a) *Standards of identity, strength, quality, and purity.* Bacitracin troches and zinc bacitracin troches are troches composed of bacitracin or zinc bacitracin, with or without ethyl aminobenzoate and with or without one or more suitable and harmless diluents, binders, lubricants, colorings, and flavorings. The potency of each troche is not less than 500 units. Its moisture content is not more than 5 percent. The bacitracin used conforms to the requirements of § 146e.401 (a), except § 146e.401 (a) (1), (2), and (4), but its potency is not less than 30 units per milligram. The zinc bacitracin used conforms to the requirements of § 146e.418 (a). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Unless each troche is enclosed in foil or plastic film and such enclosure is a tight container as defined by the U. S. P., except the provision that it shall be capable of tight reclosure, the immediate container shall be a tight container as so defined. The immediate container may also contain a desiccant separated from the troches by a plug of cotton or other like material. The composition of the immediate container, or foil or film enclosure, shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of troches shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units of bacitracin or zinc bacitracin and if it contains ethyl aminobenzoate, the quantity of such ingredient in each troche of the batch; and

(iii) The statement "Expiration date --------," the blank being filled in with the date that is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date that is 18 months or 24 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed by paragraph (a) of this section: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the circular or other labeling within or attached to the package, adequate directions and warnings for the use of such troches. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other uses of such troches by practitioners licensed by law to administer such drug will be sent to such practitioner upon request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the bacitracin or zinc bacitracin used in making such batch was completed, the number of units in each troche, the quantity of each ingredient used in making the batch, the date on which the latest assay of the troches comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency per troche and average moisture.

(ii) The bacitracin or zinc bacitracin used in making the batch; potency, moisture, toxicity, pH, and zinc content, if it is zinc bacitracin.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; one troche for each 5,000 troches in the batch, but in no case less than 20 troches or more than 100 troches, collected by taking single troches at such intervals throughout the entire time the troches are being made, that the quantities made during the intervals are approximately equal.

(ii) The bacitracin used in making the batch; six packages, each containing approximately equal portions of not less than 500 milligrams, packaged in accordance with the requirements of § 146e.401 (b).

(iii) The zinc bacitracin used in making the batch; five packages, each containing approximately equal portions of not less than 1.0 gram, packaged in accordance with the requirements of § 146e.418 (b).

(iv) In case of an initial request for certification, each other substance used in making the batch; one package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the service rendered with respect to each batch under the regulations in this part shall be:

(1) $1.00 for each troche in the sample submitted in accordance with paragraph (d) (3) (i) of this section, $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii) and (iii) of this section; and

(2) If the Commissioner considers that investigations, other than examination of such troches, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations. The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146e.405 *Bacitracin with vasoconstrictor; bacitracin with* -------- *(the blank being filled in with the common or usual name of the vasoconstrictor)*—(a) *Standards of identity, strength, quality, and purity.* Bacitracin with vasoconstrictor is a dry mixture of bacitracin and a suitable vasoconstrictor, with or without suitable and harmless buffer substances, preservatives, colorings, and flavorings, or it is a packaged combination of one immediate container of bacitracin and one immediate container of a solution of a suitable vasoconstrictor, with or without suitable and harmless buffer substances, preservatives, colorings, and flavorings. The bacitracin is of such quantity that when dissolved as directed the potency of such solution is not less than 200 units per milliliter, and maintains its labeled potency after it has been kept for 7 days at room temperature. Such solution is isotonic, and has a pH of 6.0, ±0.5. The moisture content of the dry mixture of bacitracin with vasoconstrictor is not more than 5 percent. The bacitracin used conforms to the requirements of § 146e.401 (a), except subparagraphs (2) and (4) of that paragraph. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* Each immediate container shall be a tight container as defined by the U. S. P. and shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. The immediate container of the dry mixture of bacitracin with vasoconstrictor may be packaged in combination with an immediate container of a suitable diluent.

(c) *Labeling.* Each package of bacitracin with vasoconstrictor shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and on the immediate container of the bacitracin:

(i) The batch mark;

(ii) The number of units in such container; and

(iii) If it is a packaged combination of one immediate container of bacitracin and one immediate container of a vasoconstrictor, the statement "Expiration date --------," the blank being filled in with the date which is 18 months after the month during which the batch was certified. If it is the dry mixture of bacitracin with vasoconstrictor, the statement "Expiration date ---------," the blank being filled in with the date which is 12 months after the month during which the batch was certified. Such expiration dates may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container and on the immediate container of the solution in the packaged combination:

(i) A statement giving the method of dissolving the bacitracin and, if it is not a packaged combination, a statement that distilled water U. S. P. should be used;

(ii) The potency per milliliter after the bacitracin has been dissolved therein;

(iii) The statement "Warning—Not for injection"; and

(iv) The conditions under which the solution should be stored, including a reference to its instability when stored under other conditions, and a statement "The solution may be kept at room temperature for 1 week without significant loss of potency."

(3) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch of bacitracin with vasoconstrictor shall submit with his request a statement showing the batch mark, the number of packages in such batch, the number of units in each immediate container, and (unless it was previously submitted) the date on which the latest assay of the bacitracin included in such batch was completed, the quantity of each ingredient used in making the batch of the dry mixture of bacitracin with vasoconstrictor, the quantity of each ingredient used in making the solution included in the packaged combination, and a statement that such solution conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The bacitracin included in the packaged combination and the bacitracin used in making the batch of the dry mixture of bacitracin with vasoconstrictor; potency, toxicity, moisture, and pH.

(ii) The solution after the bacitracin has been dissolved therein; potency.

(iii) The batch of the dry mixture of bacitracin with vasoconstrictor; potency and moisture.

(3) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch:

(*a*) If it contains only bacitracin and the bacitracin used has been previously submitted, or it contains bacitracin and other ingredients; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers or more than 12 immediate containers.

(*b*) If it contains only bacitracin and the bacitracin used has not been previously submitted; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 12 or more than 25 immediate containers.

Such sample shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The bacitracin used in making the batch of the dry mixture of bacitracin with vasoconstrictor; six packages, each containing approximately equal portions of not less than 500 milligrams each, packaged in accordance with the requirements of § 146e.401 (b).

(iii) In case of an initial request for certification of a batch of a dry mixture of bacitracin with vasoconstrictor, each other substance used in making the batch; one package of each containing approximately 5 grams.

(iv) In case of an initial request for certification of the packaged combination of bacitracin with vasoconstrictor, or when any change is made in the composition of such solution; five packages of the solution included in the combination.

(4) No result referred to in subparagraph (2) (i) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, are required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch of bacitracin with vasoconstrictor under the regulations in this part shall be:

(1) $4.00 for each immediate container submitted in accordance with paragraph (d) (3) (i), (ii), (iii), and (iv) of this section.

(2) If the Commissioner considers that investigations, other than examination of such packages, are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146e.406 *Bacitracin-tyrothricin troches; zinc bacitracin-tyrothricin troches.* (a) Bacitracin-tyrothricin troches and zinc bacitracin-tyrothricin troches conform to all requirements and are subject to all procedures prescribed by § 146e.404 for bacitracin troches and zinc bacitracin troches, except that:

(1) Each troche contains not less than 50 units of bacitracin or zinc bacitracin.

(2) Each troche contains not less than 1 milligram of tyrothricin.

(3) Each troche may be tableted with or without ethyl aminobenzoate.

(b) In lieu of the directions prescribed for bacitracin troches and zinc bacitracin troches by § 146e.404 (c) (1) (ii) each package shall bear on the outside wrapper or container and the immediate container the number of units of bacitracin or zinc bacitracin and the number of milligrams of tyrothricin and ethyl aminobenzoate in each troche of the batch.

§ 146e.407 *Bacitracin-tyrothricin ointment.* (a) Bacitracin - tyrothricin ointment conforms to all requirements prescribed by § 146e.402 for bacitracin ointment, and is subject to all procedures prescribed by § 146e.402 for bacitracin ointment, except paragraph (f) of that section, and except that:

(1) It contains not less than 0.5 milligram of tyrothricin per gram of ointment.

(2) In lieu of the directions prescribed for bacitracin ointment by § 146e.402 (c) (1) (ii), each package shall bear on the outside wrapper or container and on the immediate container the number of units of bacitracin and the number of milligrams of tyrothricin in each gram of the batch.

§ 146e.408 *Bacitracin ophthalmic*—(a) *Standards of identity, strength, quality, and purity.* Bacitracin ophthalmic is bacitracin, with or without one or more suitable and harmless preservatives, local anesthetics, buffer substances, and diluents. It is sterile. Its moisture content is not more than 5 percent. The bacitracin is of such quantity that when dissolved as directed in its labeling the potency of such solution is not less than 500 units per milliliter and maintains its labeled potency after it has been kept for 7 days at room temperature. Such solution has a pH of 6.5±0.5. The bacitracin used conforms to the requirements of § 146e.401 (a), except subparagraphs (2) and (4) of that paragraph. Each other ingredient used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* The immediate container of bacitracin ophthalmic shall be a tight container as defined by the U. S. P.; its closure shall be one through which a hypodermic needle cannot be introduced; and the immediate container and closure shall be of such composition as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded. Each such container shall contain not less than 5,000 units, and each may be packaged in combination with a container of the solvent, sterile distilled water U. S. P.

(c) *Labeling.* Each package shall bear, on its label or labeling as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark;

(ii) The number of units in the immediate container;

(iii) If it contains preservatives or local anesthetics, the name and quantity of each such ingredient;

(iv) The statement "Expiration date ____________," the blank being filled in with the date which is 12 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container;

(v) The statement "Warning—Not for injection."

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription," unless it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled.

(ii) If it is packaged for dispensing and it is intended for use by man, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(3) On the label or labeling, if a local anesthetic is present, after the name "bacitracin ophthalmic," wherever it appears, the words "with ________" (the blank being filled in with the common or usual name of the local anesthetic), in juxtaposition with such name.

(4) On the circular or other labeling within or attached to the package, if it is packaged for dispensing and it is intended solely for veterinary use and is conspicuously so labeled, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Requests for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the bacitracin used in making such batch was completed, the number of units in each immediate container, the date on which the latest assay of the drug comprising such batch was completed, the quantity of each other ingredient used in making the batch, and a statement that each such ingredient used conforms to the requirements prescribed therefor by this section. If such batch or any part thereof is to be packaged with a solvent, such request shall also be accompanied by a statement that such solvent conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; potency, sterility, moisture, and pH of the solution prepared as directed in its labeling.

(ii) The bacitracin used in making the batch; potency, toxicity, moisture, and pH.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request in the quantities hereinafter indicated accurately representative samples of the following:

(i) The batch:

(*a*) For all tests except sterility; one immediate container for each 5,000 immediate containers in the batch, but in no case less than 5 immediate containers or more than 12 immediate containers.

(*b*) For sterility testing; 10 immediate containers.

Such samples shall be collected by taking single immediate containers at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The bacitracin used in making the batch; 6 packages, each containing approximately equal portions of not less than 500 milligrams packaged in accordance with the requirements of § 146e.401 (b).

(iii) In case of an initial request for certification, each other ingredient used in making the batch; one package of each, containing approximately 5.0 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container or package in the samples submitted in accordance with paragraph (d) (3) (i) (*a*), (ii), and (iii) of this section.

(2) If the Commissioner considers that investigations other than examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146e.409 *Bacitracin - polymyxin ointment.* (a) Bacitracin-polymyxin ointment conforms to all requirements prescribed by § 146e.402 for bacitracin ointment, and is subject to all procedures prescribed by § 146e.402 for bacitracin ointment, except paragraph (f) of that section, and except that:

(1) Its content of bacitracin is not less than 200 units per gram.

(2) It contains not less than 4,000 units of polymyxin B per gram. The polymyxin B used conforms to the requirements prescribed for polymyxin B by § 146b.107 (a) of this chapter.

(3) Its moisture content is not more than 0.5 percent.

(4) If it is in liquid form, it shall be packaged in immediate containers of transparent glass which meet the test for tight containers as defined by the U. S. P.

(5) In lieu of the labeling prescribed by § 146e.402 (c) (1) (ii) and (iv), each package shall bear on the outside wrapper or container and the immediate container the number of units of bacitracin and the number of units of polymyxin B in each gram of the batch and the statement "Expiration date ____________," the blank being filled in with the date which is 12 months after the month during which the batch was certified, except that if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for 18 months or 24 months or 36 months at room temperature such drug as prepared by him complies with the standards of identity, strength, quality, and purity prescribed for the drug, the blank shall be filled in with the date which is 18 months or 24 months or 36 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(6) In addition to complying with the requirements of § 146e.402 (c), if it is in liquid form, each package shall bear on the outside wrapper or container and the immediate container, the statements "Shake well" and "Not for injection."

(7) In addition to complying with the requirements of § 146e.402 (d), a person who requests certification of a batch of bacitracin - polymyxin ointment shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and date of the latest tests and assays of the polymyxin used in making the batch for potency and toxicity. He shall also submit in connection with his request a sample consisting of not less than 6 packages of bacitracin-polymyxin ointment and (unless it was previously submitted) a sample consisting of 5 packages containing equal portions of not less than 0.5 gram each of the polymyxin used in making the batch.

(b) The fee for the services rendered with respect to each immediate container in the sample of polymyxin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146e.410 *Bacitracin-neomycin tablets; zinc bacitracin-neomycin tablets.* (a) Bacitracin-neomycin tablets and zinc bacitracin-neomycin tablets conform to all requirements and are subject to all procedures prescribed by § 146e.403 for bacitracin tablets and zinc bacitracin tablets, except that:

(1) Each tablet contains not less than 2,500 units of bacitracin or zinc bacitracin.

(2) Each tablet contains not less than 25 milligrams of neomycin. The neomycin used is produced by the growth of Streptomyces fradiae, has a potency of not less than 330 micrograms (one Waksman unit is equivalent to 3.3 micrograms of the base) per milligram, is nontoxic, has a moisture content of not more than 8 percent, and its pH in an aqueous solution 33 milligrams per milliliter is not less than 5.0 and not more than 7.5.

(3) In lieu of the labeling prescribed for bacitracin tablets and zinc bacitracin tablets by § 146e.403 (c) (1) (ii), each package shall bear on the outside wrapper or container and the immediate container the number of units of bacitracin or zinc bacitracin and the number of milligrams of neomycin in each tablet of the batch.

(4) In addition to complying with the requirements of § 146e.403 (d), a person who requests certification of a batch shall submit with his request a statement showing the number of units of bacitracin or zinc bacitracin and the number of milligrams of neomycin in each tablet of the batch, the batch mark, and (unless it was previously submitted) the results and the date of the latest tests and assays

of the neomycin used in making the batch for potency, toxicity, moisture, and pH. He shall also submit in connection with his request a sample consisting of not less than 30 tablets and (unless it was previously submitted) a sample consisting of 5 packages containing approximately equal portions of not less than 0.5 gram each of the neomycin used in making such batch.

(b) The fee for the services rendered with respect to each immediate container in the sample of neomycin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146e.411 *Bacitracin-neomycin ointment; zinc bacitracin-neomycin ointment.* (a) Bacitracin-neomycin ointment and zinc bacitracin-neomycin ointment conform to all requirements and are subject to all procedures prescribed by § 146e.402 for bacitracin ointment and zinc bacitracin ointment, except paragraph (f) of that section, and except that:

(1) It contains not less than 3.50 milligrams of neomycin per gram. The neomycin used conforms to the requirements prescribed for neomycin by § 146e.410 (a) (2).

(2) In lieu of the labeling prescribed by § 146e.402 (c) (1) (ii) and (iv), each package shall bear on the outside wrapper or container and the immediate container the number of units of bacitracin or zinc bacitracin and the number of milligrams of neomycin in each gram of the batch and the statement "Expiration date ____," the blank being filled in with the date which is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 18 months or 24 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug as prepared by him is stable for such period of time: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(3) In addition to complying with the requirements of § 146e.402 (d), a person requesting certification of a batch shall submit with his request a statement showing the number of units of bacitracin or zinc bacitracin and the number of milligrams of neomycin in each gram of ointment, the batch mark, and (unless it was previously submitted) the results and the date of the latest tests and assays of the neomycin used in making the batch for potency, toxicity, moisture, and pH. He shall also submit in connection with his request a sample consisting of not less than 6 packages of the ointment and (unless it was previously submitted) a sample consisting of 5 packages containing approximately equal portions of not less than 0.5 gram each of the neomycin used in making such batch.

(b) The fee for the services rendered with respect to each immediate container in the sample of neomycin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146e.412 *Bacitracin-polymyxin tablets.* (a) Bacitracin-polymyxin tablets conform to all requirements prescribed by § 146e.403 for bacitracin tablets, and are subject to all procedures prescribed by § 146e.403 for bacitracin tablets except that:

(1) Each tablet contains not less than 400 units of bacitracin.

(2) Each tablet contains not less than 8,000 units of polymyxin B sulfate. The polymyxin B used conforms to the requirements prescribed for polymyxin by § 146b.107 (a) of this chapter.

(3) In lieu of the labeling prescribed for bacitracin tablets by § 146e.403 (c) (1) (ii), each package shall bear on the outside wrapper or container and the immediate container the number of units of bacitracin and the number of units of polymyxin B in each tablet of the batch.

(4) In addition to complying with the requirements of § 146e.403 (d) a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the polymyxin B used in making the batch for potency and toxicity. He shall also submit in connection with his request a sample consisting of not less than 30 tablets of such batch, and (unless it was previously submitted) a sample consisting of 5 packages, each containing approximately equal portions of not less than 0.5 gram of the polymyxin B used in making the batch.

(b) The fee for the services rendered with respect to each container in the sample of polymyxin B submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146e.413 *Bacitracin-neomycin troches, zinc bacitracin-neomycin troches.* Bacitracin-neomycin troches and zinc bacitracin-neomycin troches conform to all requirements and are subject to all procedures prescribed by § 146e.410 for bacitracin-neomycin tablets, except that:

(a) Each troche contains not less than 200 units of bacitracin or zinc bacitracin. The zinc bacitracin used conforms to the requirements prescribed by § 146e.418 (a).

(b) Each troche contains not less than 2.5 milligrams of neomycin.

(c) Each troche may be tableted with or without one or more suitable and harmless local anesthetics, preservatives, and chemical antimicrobial agents.

(d) In addition to the labeling prescribed for bacitracin-neomycin tablets, if it contains one or more of the ingredients specified in paragraph (c) of this section, each package shall bear on the outside wrapper or container and the immediate container the name and quantity of each such ingredient in each troche of the batch.

(e) If zinc bacitracin is used in the manufacture of the batch, the person who requests certification of a batch shall submit with his request results and the dates of the latest tests of the zinc bacitracin used in making the batch for potency, toxicity, moisture, pH, and zinc content. He shall also submit in connection with his request (unless it was previously submitted) a sample consisting of 5 packages, each containing approximately 1.0 gram of the zinc bacitracin used in making the batch.

(f) The fee for the services rendered with respect to each package of the sample submitted in accordance with paragraph (e) of this section shall be $4.00.

§ 146e.414 *Bacitracin-neomycin with vasoconstrictor; bacitracin-neomycin with ________ (the blank being filled in with the common or usual name of the vasoconstrictor).* (a) Bacitracin-neomycin with vasoconstrictor conforms to all requirements prescribed by § 146e.405 for bacitracin with vasoconstrictor and is subject to all procedures prescribed by § 146e.405 for bacitracin with vasoconstrictor, except that:

(1) When prepared as directed in its labeling it contains not less than 3.5 milligrams of neomycin per milliliter. The neomycin used conforms to the requirements prescribed for neomycin by § 146e.410 (a) (2).

(2) In lieu of the labeling prescribed by § 146e.405 (c) (1) (ii) and (iii), each package shall bear on the outside wrapper or container and the immediate container the number of units of bacitracin and the number of milligrams of neomycin in each container and the statement "Expiration date ______________," the blank being filled in with the date which is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date which is 18 months or 24 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that such drug as prepared by him is stable for such period of time: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container. Furthermore, in lieu of the 1-week storage statement for the solution prescribed by § 146e.405 (c) (2) (iv), the labeling may bear a 3-week storage statement if the person who requests certification has submitted to the Commissioner results of tests and assays showing that solutions of the drug as prepared by him are stable for such period of time after storage at room temperature.

(3) In addition to complying with the requirements of § 146e.405 (d), a person who requests certification of a batch of bacitracin-neomycin with vasoconstrictor shall submit with his request a statement showing the number of units of bacitracin and the number of milligrams of neomycin in each immediate container, the batch mark, and (unless it was previously submitted) the results and the date of the latest tests and assays of the neomycin used in making the batch for potency, toxicity, moisture, and pH. He shall also submit in connection with his request a sample consisting of not less than 6 packages of the bacitra-

cin-neomycin with vasoconstrictor and (unless it was previously submitted) a sample consisting of 5 packages containing approximately equal portions of not less than 0.5 gram each of the neomycin used in making such batch.

(b) The fee for the services rendered with respect to each immediate container in the sample of neomycin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146e.415 *Bacitracin-polymyxin troches; zinc bacitracin-polymyxin troches.* Bacitracin-polymyxin troches and zinc bacitracin-polymyxin troches conform to all requirements and are subject to all procedures prescribed by § 146e.404 for bacitracin troches and zinc bacitracin troches, except that:

(a) Each troche contains not less than 50 units of bacitracin or zinc bacitracin.

(b) Each troche contains not less than 1,000 units of polymyxin B sulfate. The polymyxin B used conforms to the requirements prescribed for polymyxin by § 146b.107 (a) of this chapter.

(c) Each troche may be tableted with or without one or more suitable and harmless local anesthetics.

(d) In addition to the labeling prescribed for bacitracin troches and zinc bacitracin troches, each package shall bear on its label or labeling the number of units of polymyxin B; and if it contains one or more local anesthetics, the name and quantity of each such ingredient in each troche of the batch.

(e) In addition to complying with the requirements of § 146e.404 (d), a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the polymyxin B used in making the batch for potency and toxicity. He shall also submit in connection with his request a sample consisting of not less than 30 troches and (unless it was previously submitted) a sample consisting of 5 packages, each containing approximately equal portions of not less than 500 milligrams of the polymyxin used in making the batch.

(f) The fee for the services rendered with respect to each container in the sample of polymyxin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146e.416 *Bacitracin methylene disalicylate*—(a) *Standards of identity, strength, quality, and purity.* Bacitracin methylene disalicylate is the methylene disalicylate salt of a kind of bacitracin. It is so purified and dried that:

(1) Its potency is not less than 14 units per milligram.

(2) It is nontoxic.

(3) Its moisture content is not more than 5 percent.

(4) Its pH in a saturated aqueous solution is not less than 3.5 and not more than 5.0.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P. The composition of the immediate containers shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused which are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of bacitracin methylene disalicylate shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of units of bacitracin per gram, the number of grams of bacitracin activity per pound, and the weight of the drug in the immediate container.

(iii) The statement "Expiration date ----------," the blank being filled in with the date which is 24 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(iv) The statement "For veterinary use only."

(2) On the circular or other labeling within or attached to the package, adequate directions and warnings for the veterinary use of such drug by the laity.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of units of bacitracin activity per gram, and the number of grams of bacitracin activity per pound. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, toxicity, moisture, and pH.

(2) Such person shall submit with his request an accurately representative sample of the batch, consisting of 5 packages each containing approximately 5 grams taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance with paragraph (d) (2) of this section.

(2) If the Commissioner considers that investigations other than the examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigation.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146e.417 *Powder bacitracin methylene disalicylate and streptomycin sulfate oral veterinary*—(a) *Standards of identity, strength, quality, and purity.* Powder bacitracin methylene disalicylate and streptomycin sulfate oral veterinary is a mixture of bacitracin methylene disalicylate and streptomycin sulfate oral veterinary, with or without one or more suitable and harmless adsorbent ingredients, diluents, colorings, and flavorings. Each gram contains not less than 200 units of bacitracin activity and not less than 20 milligrams of streptomycin activity. Its moisture content is not more than 7.5 percent. The bacitracin methylene disalicylate used conforms to the requirements prescribed by § 146e.416 (a). The streptomycin sulfate oral veterinary used conforms to the standards prescribed by § 146b.114 (a) of this chapter. Each other ingredient used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P. and shall be of such composition that they will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of units of bacitracin activity and the number of milligrams of streptomycin activity per gram and the total number of grams in the immediate container.

(iii) The statement "Expiration date ———," the blank being filled in with the date which is 12 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(iv) The statement "For oral veterinary use only."

(v) If it contains adsorbent ingredients, the name of each.

(2) On the circular or other labeling within or attached to the package, adequate directions and warnings for the veterinary use of such drug by the laity. Such circular or other labeling may also bear a statement that a brochure or other printed matter containing information for other veterinary uses of such drug by a veterinarian licensed by law to administer it will be sent to such veterinarian on request.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch marks and (unless they were previously submitted) the dates on which the latest assays of the bacitracin methylene disalicylate and streptomycin sulfate oral veterinary used in making such batch were completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each other ingredient used conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; units of bacitracin activity per gram, milligram of streptomycin activity per gram, and moisture.

(ii) The bacitracin methylene disalicylate and the streptomycin sulfate oral veterinary used in making the batch; potency, toxicity, moisture, and pH.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 6 immediate containers or more than 12 immediate containers, unless each such container is packaged to contain more than 30 grams, in which case the sample shall consist of 30 grams for each 5,000 immediate containers in the batch, but in no case less than 6 30-gram portions or more than 12 30-gram portions. Such samples shall be collected by taking single immediate containers or 30-gram portions at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The bacitracin methylene disalicylate used in making the batch; 5 packages containing approximately equal portions of not less than 5 grams each, packaged in accordance with the requirements of § 146e.416 (b).

(iii) The streptomycin sulfate oral veterinary used in making the batch; 5 packages containing approximately equal portions of not less than 1.0 gram each, packaged in accordance with the requirements of § 146b.114 (b) of this chapter.

(iv) In case of an initial request for certification, the other ingredients used in making the batch; 1 package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) and (iii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (3) (i), (ii), (iii), and (iv) of this section.

(2) If the Commissioner considers that investigations other than examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with the requirements of § 146.8 (d) of this chapter.

§ 146e.418 *Zinc bacitracin (bacitracin zinc salt)*—(a) *Standards of identity, strength, quality, and purity.* Zinc bacitracin is the zinc salt of a kind of bacitracin or a mixture of two or more such salts. It is so purified and dried that:

(1) Its potency is not less than 40 units per milligram.

(2) It is nontoxic.

(3) Its moisture content is not more than 5 percent.

(4) Its pH is not less than 6.0 and not more than 7.5.

(5) Its zinc content is not more than 10 percent by weight on a moisture-free basis.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P. The composition of the immediate containers shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package of zinc bacitracin shall bear on its outside wrapper or container and the immediate container:

(1) The batch mark.

(2) The number of units of bacitracin activity per milligram of zinc bacitracin and the number of grams of the drug in the immediate container.

(3) The statement "Expiration date ------," the blank being filled in with the date which is 24 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(4) The statement "For use only in the manufacture of nonparenteral drugs."

(5) The statement "Caution: Federal law prohibits dispensing without prescription."

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in the batch, the number of units of bacitracin activity per milligram of zinc bacitracin, the zinc content, and the total number of grams of zinc bacitracin in each package. Such request shall be accompanied or followed by the results of tests and assays made by him on the batch for potency, toxicity, moisture, pH, and zinc content.

(2) Such person shall also submit with his request an accurately representative sample of the batch, consisting of 5 packages each containing approximately 1.0 gram taken from a different part of such batch, and each shall be packaged in accordance with the requirements of paragraph (b) of this section.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the sample submitted in accordance wih paragraph (d) (2) of this section.

(2) If the Commissioner considers that investigations other than the examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146e.419 *Bacitracin-neomycin-polymyxin troches; zinc bacitracin-neomycin-polymyxin troches*—(a) *Standards of identity, strength, quality, and purity.* Bacitracin-neomycin-polymyxin troches and zinc bacitracin-neomycin-polymyxin troches are troches composed of bacitracin or zinc bacitracin, neomycin, and polymyxin B with one or more suitable and harmless diluents, binders, lubricants, colorings, and flavorings. The potency of each troche is not less than 200 units of bacitracin or zinc bacitracin, 5.0 milligram of neomycin, and 2,000 units of polymyxin B. Its moisture content is not more than 5 percent. The bacitracin used conforms to the standards prescribed therefor by § 146e.401 (a) except § 146e.401 (a) (1), (2), and (4), but its potency is not less than 30 units per milligram. The zinc bacitracin used conforms to the standards prescribed therefor by § 146e.418 (a). The neomycin used conforms to the standards prescribed therefor by § 146e.410 (a) (2). The polymyxin B used conforms to the standards prescribed therefor by § 146b.107 (a) of this chapter. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* It shall be packaged in accordance with the requirements prescribed by § 146e.403 (b).

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of units of bacitracin or zinc bacitracin, the number of milligrams of neomycin, and the number of units of polymyxin B in each troche of the batch.

(iii) The statement "Expiration date ----------," the blank being filled in with the date that is 12 months after the month during which the batch was certified, except that the blank may be filled in with the date that is 18 months or 24 months after the month during which the batch was certified if the person who requests certification has submitted to the Commissioner results of tests and assays showing that after having been stored for such period of time such drug as prepared by him complies with the standards prescribed therefor by paragraph (a) of this section: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(2) On the outside wrapper or container:

(i) The statement "Caution: Federal law prohibits dispensing without prescription."

(ii) If it is packaged for dispensing, a reference specifically identifying a readily available medical publication containing information (including contraindications and possible sensitization) adequate for the use of such drug by practitioners licensed by law to administer it; or a reference to a brochure or other printed matter containing such information, and a statement that such brochure or other printed matter will be sent on request: *Provided, however,* That this reference may be omitted if the information is contained in a circular or other labeling within or attached to the package.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless they were previously submitted) the dates on which the latest assays of the bacitracin or zinc bacitracin, neomycin, and polymyxin B used in making such batch were completed, the potency of each troche, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each ingredient used in making the batch conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided in subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch; average potency of bacitracin or zinc bacitracin, neomycin, and polymyxin per troche, and average moisture.

(ii) The bacitracin used in making the batch; potency, toxicity, moisture, and pH.

(iii) The zinc bacitracin used in making the batch; potency, toxicity, moisture, pH, and zinc content.

(iv) The neomycin used in making the batch; potency, toxicity, moisture, and pH.

(v) The polymyxin used in making the batch; potency and toxicity.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch; 1 troche for each 5,000 troches in the batch, but in no case less than 40 troches or more than 100 troches, collected by taking single troches at such intervals throughout the entire time of tableting that the quantities tableted during the intervals are approximately equal.

(ii) The bacitracin used in making the batch; 6 packages, each containing approximately equal portions of not less than 0.5 gram, packaged in accordance with the requirements of § 146e.401 (b).

(iii) The zinc bacitracin used in making the batch; 5 packages, each containing approximately equal portions of not less than 1.0 gram, packaged in accordance with the requirements of § 146e.418 (b).

(iv) The neomycin used in making the batch; 5 packages, each containing approximately equal portions of not less than 0.5 gram.

(v) The polymyxin used in making the batch; 5 packages, each containing approximately equal portions of not less than 0.5 gram.

(vi) In case of an initial request for certification, each other ingredient used in making the batch; 1 package of each, containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii), (iii), (iv), and (v) of this paragraph, and no samples referred to in subparagraph (3) (ii), (iii), (iv), and (v) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $1.00 for each troche in the sample submitted in accordance with paragraph (d) (3) (i) of this section; $4.00 for each package in the samples submitted in accordance with paragraph (d) (3) (ii), (iii), (iv), (v), and (vi) of this section.

(2) If the Commissioner considers that investigations, other than examination of such troches and packages are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with § 146.8 (d) of this chapter.

§ 146e.420 *Bacitracin-tyrothricin-neomycin troches; zinc bacitracin-tyrothricin-neomycin troches.* Bacitracin-tyrothricin-neomycin troches and zinc bacitracin-tyrothricin-neomycin troches conform to all requirements and are subject to all procedures prescribed by § 146e.413 for bacitracin-neomycin troches or zinc bacitracin-neomycin troches, except that:

(a) Each troche contains not less than 50 units of bacitracin or zinc bacitracin.

(b) Each troche contains not less than 1 milligram of tyrothricin.

(c) They may contain cortisone or a suitable derivative of cortisone.

(d) In addition to the labeling prescribed for bacitracin-neomycin troches and zinc bacitracin-neomycin troches, each package shall bear on the outside wrapper or container and the immediate container the number of milligrams of tyrothricin in each troche of the batch, and if it contains cortisone or a derivative of cortisone, the name and quantity of each such substance.

§ 146e.421 *Bactracin-neomycin-polymyxin tablets.* (a) Bacitracin-neomycin-polymyxin tablets conform to all requirements and are subject to all procedures prescribed by § 146e.412 for bacitracin-polymyxin tablets, except that:

(1) Each tablet contains not less than 6 milligrams of neomycin. The neomycin used conforms to the requirements prescribed therefor by § 146e.410 (a) (2).

(2) In lieu of the labeling prescribed for bacitracin-polymyxin tablets by § 146e.412 (a) (3), each package shall bear on the outside wrapper or container and the immediate container the number of units of bacitracin, the number of units of polymyxin B, and the number of milligrams of neomycin in each tablet of the batch.

(3) In addition to complying with the requirements of § 146e.412 (a) (4), a person who requests certification of a batch shall submit with his request a statement showing the batch mark and (unless it was previously submitted) the results and the date of the latest tests and assays of the neomycin used in making the batch for potency, toxicity, moisture, and pH. He shall also submit in connection with his request a sample consisting of 5 packages containing approximately equal portions of not less than 0.5 gram each of the neomycin used in making such batch.

(b) The fee for the services rendered with respect to each immediate container in the sample of neomycin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146e.422 *Bacitracin-polymyxin-neomycin ointment.* (a) Bacitracin-polymyxin-neomycin ointment conforms to all requirements prescribed by § 146e.409 for bacitracin-polymyxin ointment, and is subject to all procedures prescribed by § 146e.409 for bacitracin-polymyxin ointment, except that:

(1) Its content of neomycin is not less than 3.0 milligrams per gram. The neomycin used conforms to the standards prescribed by § 146e.410 (a) (2).

(2) It may contain one or more suitable and harmless chemical antimicrobial agents.

(3) In addition to the labeling prescribed by § 146e.409 (a) (5), each package shall bear on the outside wrapper or container and the immediate container the number of milligrams of neomycin in each gram of the batch.

(4) In addition to complying with the requirements of § 146e.409 (a) (7), a person who requests certification of a batch of bacitracin-polymyxin-neomycin

ointment shall submit with his request a statement showing the batch mark and (unless they were previously submitted) the results and date of the latest tests and assays of the neomycin used in making the batch for potency, toxicity, moisture, and pH. He shall also submit in connection with his request a sample consisting of not less than 7 packages of bacitracin-polymyxin-neomycin ointment and (unless it was previously submitted) a sample consisting of 5 packages of the neomycin used in making the batch, each containing approximately 0.5 gram.

(b) The fee for the services rendered with respect to each immediate container in the sample of neomycin submitted in accordance with the requirements prescribed therefor by paragraph (a) (4) of this section shall be $4.00.

§ 146e.423 *Soluble bacitracin methylene disalicylate*—(a) *Standards of identity, strength, quality, and purity.* Soluble bacitracin methylene disalicylate is a mixture of bacitracin methylene disalicylate, sodium carbonate, and sodium bicarbonate, with or without suitable and harmless diluents. It contains the equivalent of not less than 25 grams of the bacitracin master standard per pound. Its moisture content is not more than 8.5 percent. Its pH in an aqueous solution containing 200 units per milliliter is not less than 8.5 and not more than 9.5. The bacitracin methylene disalicylate used conforms to the requirements of § 146e.416 (a). Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging; labeling; request for certification, samples; fees.* Soluble bacitracin methylene disalicylate conforms to all requirements and procedures prescribed for bacitracin methylene disalicylate by § 146e.416 (b), (c), (d), and (e), except that the person who requests certification of a batch shall submit with his request (unless previously submitted) a sample consisting of 5 immediate containers, each containing approximately 5 grams, of the bacitracin methylene disalicylate used in making the batch.

(c) *Exemption of soluble bacitracin methylene disalicylate from certification.* Soluble bacitracin methylene disalicylate that conforms to the requirements of paragraphs (a) (except that it may contain one or more essential vitamin and mineral substances for nutritive purposes) and (b) of this section shall be exempt from the requirements of sections 502 (l) and 507 of the act if it complies with all the following conditions:

(1) Its label bears an expiration date that is not more than 24 months after the month during which the batch was last assayed and released by the manufacturer.

(2) If it contains added vitamins or minerals, its label bears the name and quantity of each such substance and a statement that such substances are present only for furnishing additional vitamins and minerals while animals are eating less feed.

(3) The label bears a statement that solutions prepared with the drug are stable for not more than 24 hours.

(4) The circular or other labeling within or attached to the package bears information that only the antibiotic is intended for the prevention or treatment of the following conditions, and further, bears directions and warnings adequate for such use:

(i) Chronic respiratory disease (airsac infection) in chickens.

(ii) Blue comb (mud fever, nonspecific infectious enteritis) in poultry.

(iii) Infectious sinusitis in poultry.

(iv) Bacterial enteritis in swine.

§ 146e.424 *Bacitracin-neomycin-polymyxin with vasoconstrictor; bacitracin-neomycin-polymyxin with ------------ (the blank being filled in with the common or usual name of the vasoconstrictor).* (a) Bacitracin-neomycin-polymyxin with vasoconstrictor conforms to all requirements and is subject to all procedures prescribed by § 146e.414 for bacitracin-neomycin with vasoconstrictor, except that:

(1) When prepared as directed in its labeling, each milliliter shall contain not less than 50 units of bacitracin 3.5 milligrams of neomycin, and 1,000 units of polymyxin B. The polymyxin B used conforms to the requirements prescribed for polymyxin B by § 146b.107 (a) of this chapter.

(2) It may contain the enzyme hyaluronidase.

(3) It may be a packaged combination of one immediate container of dry components of the drug and one immediate container of a solution of components of the drug; but in no case shall bacitracin or hyaluronidase be a component of such solution of the packaged combination.

(4) The moisture content of the dry components of the drug is not more than 2.5 percent.

(5) In addition to the labeling prescribed by § 146e.414 (a) (2), each package shall bear on the outside wrapper or container and the immediate container the number of units of polymyxin B in each container, and if it contains hyaluronidase the quantity of such ingredient in each container.

(6) On the label or labeling, if it contains hyaluronidase, after the name "bacitracin - neomycin - polymyxin with vasoconstrictor," wherever it appears, the words "and hyaluronidase," shall appear in juxtaposition with such name.

(7) In addition to complying with the requirements of § 146e.414 (a) (3), a person who requests certification of a batch shall submit with his request a statement showing the number of units of polymyxin B in each immediate container, the batch mark, and (unless it was previously submitted) the results and the date of the latest tests and assays of the polymyxin used in making the batch for potency and toxicity. He shall also submit in connection with his request a sample consisting of not less than 7 packages of the bacitracin- neomycin-polymyxin with vasoconstrictor, and (unless it was previously submitted) a sample consisting of 5 packages containing approximately equal portions of not less than 0.5 gram each of the polymyxin used in making the batch.

(b) The fee for the services rendered with respect to each immediate container in the sample of polymyxin submitted in accordance with the requirements prescribed therefor by this section shall be $4.00.

§ 146e.425 *Bacitracin powder*—(a) *Standards of identity, strength, quality, and purity.* Bacitracin powder is bacitracin, with or without suitable and harmless buffer substances, preservatives, diluents, colorings, and flavorings. It contains the equivalent of not less than 10 grams of the bacitracin master standard per pound. Its moisture content is not more than 5 percent. The bacitracin used conforms to the requirements of § 146e.401 (a), except § 146e.401 (a) (1), (2), and (4), but its potency is not less than 30 units per milligram. Each other substance used, if its name is recognized in the U. S. P. or N. F., conforms to the standards prescribed therefor by such official compendium.

(b) *Packaging.* In all cases the immediate containers shall be tight containers as defined by the U. S. P. The composition of the immediate containers shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor in applicable standards, except that minor changes so caused that are normal and unavoidable in good packaging, storage, and distribution practice shall be disregarded.

(c) *Labeling.* Each package shall bear on its label or labeling, as hereinafter indicated, the following:

(1) On the outside wrapper or container and the immediate container:

(i) The batch mark.

(ii) The number of units of bacitracin per gram, the number of grams of bacitracin activity per pound, and the weight of the drug in the immediate container.

(iii) The statement "Expiration date --------," the blank being filled in with the date that is 18 months after the month during which the batch was certified: *Provided, however,* That such expiration date may be omitted from the immediate container if such immediate container is packaged in an individual wrapper or container.

(iv) The statement "For oral veterinary use only."

(2) On the circular or other labeling within or attached to the package, adequate directions and warnings for the veterinary use of such drug by the laity.

(d) *Request for certification; samples.* (1) In addition to complying with the requirements of § 146.2 of this chapter, a person who requests certification of a batch shall submit with his request a statement showing the batch mark, the number of packages of each size in such batch, the batch mark and (unless it was previously submitted) the date on which the latest assay of the bacitracin used in making such batch was completed, the quantity of each ingredient used in making the batch, the date on which the latest assay of the drug comprising such batch was completed, and a statement that each other ingredient used conforms to the requirements prescribed therefor by this section.

(2) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request results of the tests and

assays listed after each of the following, made by him on an accurately representative sample of:

(i) The batch: Units of bacitracin per gram, and moisture.

(ii) The bacitracin used in making the batch: Potency, toxicity, moisture, and pH.

(3) Except as otherwise provided by subparagraph (4) of this paragraph, such person shall submit in connection with his request, in the quantities hereinafter indicated, accurately representative samples of the following:

(i) The batch: 1 immediate container for each 5,000 immediate containers in the batch, but in no case less than 6 immediate containers or more than 12 immediate containers, unless each such container is packaged to contain more than 30 grams, in which case the sample shall consist of 30 grams for each 5,000 immediate containers in the batch, but in no case less than six 30-gram portions or more than twelve 30-gram portions. Such samples shall be collected by taking single immediate containers or 30-gram portions at such intervals throughout the entire time of packaging the batch that the quantities packaged during the intervals are approximately equal.

(ii) The bacitracin used in making the batch: 6 packages, each containing approximately equal portions of not less than 500 milligrams, packaged in accordance with the requirements of § 146e.401 (b).

(iii) In case of an initial request for certification, each other substance used in making the batch: 1 package of each containing approximately 5 grams.

(4) No result referred to in subparagraph (2) (ii) of this paragraph, and no sample referred to in subparagraph (3) (ii) of this paragraph, is required if such result or sample has been previously submitted.

(e) *Fees.* The fee for the services rendered with respect to each batch under the regulations in this part shall be:

(1) $4.00 for each immediate container in the samples submitted in accordance with paragraph (d) (3) (i), (ii), and (iii) of this section.

(2) If the Commissioner considers that investigations other than examination of such immediate containers are necessary to determine whether or not such batch complies with the requirements of § 146.3 of this chapter for the issuance of a certificate, the cost of such investigations.

The fee prescribed by subparagraph (1) of this paragraph shall accompany the request for certification unless such fee is covered by an advance deposit maintained in accordance with the requirements of § 146.8 (d) of this chapter.

(f) *Exemption of bacitracin powder from certification.* Bacitracin powder that conforms to the requirements of paragraphs (a) (except that it may contain one or more essential vitamin and mineral substances for nutritive purposes), (b), and (c) of this section, except paragraph (c) (1) (iii), shall be exempt from the requirements of sections 502 (l) and 507 of the act if it complies with all the following conditions:

(1) Its label bears an expiration date that is not more than 18 months after the month during which the batch was last assayed and released by the manufacturer.

(2) If it contains added vitamins or minerals, its label bears the name and quantity of each such substance and a statement that such substances are present only for furnishing additional vitamins and minerals while animals are eating less feed.

(3) The label bears a statement that solutions prepared with the drug are stable for not more than 24 hours.

(4) The circular or other labeling referred to in paragraph (c) (2) of this section bears information that only the antibiotic is intended for the prevention or treatment of the following conditions, and further, bears directions and warnings adequate for such use:

(i) Chronic respiratory disease (air-sac infection) in chickens.

(ii) Blue comb (mud fever, nonspecific infectious enteritis) in poultry.

(iii) Infectious sinusitis in poultry.

(iv) Bacterial enteritis in swine.

§ 146e.426 *Tablets bacitracin methylene disalicylate and streptomycin sulfate oral veterinary.* Tablets bacitracin methylene disalicylate and streptomycin sulfate oral veterinary are tablets that conform to all requirements and are subject to all procedures prescribed by § 146e.417 for powder bacitracin methylene disalicylate and streptomycin sulfate oral veterinary, except that:

(a) Each tablet shall contain not less than 200 units of bacitracin activity and not less than 20 milligrams of streptomycin activity.

(b) In lieu of the directions for labeling prescribed by § 146e.417 (c) (1) (ii), each package shall bear on the outside wrapper or container and the immediate container the quantity of each antibiotic in each tablet.

(c) In lieu of the directions for sampling the batch as prescribed in § 146e.417 (d) (3) (i), the sample shall consist of not less than 30 tablets and not more than 100 tablets.

(d) The fee for the services rendered with respect to each tablet in the sample submitted in accordance with the requirements prescribed therefor by paragraph (c) of this section shall be $1.00.

PART 164—CERTIFICATION OF BATCHES OF DRUGS COMPOSED WHOLLY OR PARTLY OF INSULIN

Sec.
164.1 Definitions and interpretations of terms.
164.2 Requests for certification; samples; storage; approvals preliminary to certification.
164.3 Certifications.
164.4 Conditions on the effectiveness of certificates.
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164.9 Authority to refuse certification service.
164.10 Fees.
164.11 Standards of quality and purity for protamine.
164.12 Standards of quality and purity for globin hydrochloride.
164.13 Standards of identity, strength, quality, and purity for lente insulin.
164.14 Tests and methods of assay.

AUTHORITY: §§ 164.1 to 164.14 issued under sec. 701, 52 Stat. 1055; 21 U. S. C. 371. Interpret or apply sec. 506, 55 Stat. 851; 21 U. S. C. 356.

§ 164.1 *Definitions and interpretations of terms.* For the purpose of the regulations in this part:

(a) The term "insulin" means the active principle of pancreas which affects the metabolism of carbohydrate in the animal body and which is of value in the treatment of diabetes mellitus.

(b) The term "insulin U. S. P." means the insulin injection recognized in the official United States Pharmacopeia, including supplements thereto.

(c) The term "protamine zinc insulin" means the protamine zinc insulin injection recognized in the official United States Pharmacopeia, including supplements thereto.

(d) The term "globin zinc insulin" means the globin zinc insulin injection recognized in the official United States Pharmacopeia, including supplements thereto.

(e) The term "isophane insulin" means the isophane insulin injection recognized in the official United States Pharmacopeia, including supplements thereto.

(f) The term "lente insulin" means the insulin preparation described in § 164.13.

(g) The term "master lot" means a quantity (which is purified and which has been mixed in one container so as to be homogeneous) of:

(1) A concentrated solution of insulin; or

(2) The insulin-containing solids, in amorphous or crystalline form, derived from one or more such solutions.

(h) The term "batch" means a quantity of a drug, in labeled packages, of uniform composition and intended for administration without further change, in which the sole insulin-containing ingredient is a single dilution (which has been mixed in one container so as to be homogeneous) of:

(1) A single master lot or part thereof; or

(2) A mixture of two or more master lots or parts thereof;

except that such term means a portion of such quantity when certification of such portion is requested.

(i) The term "master lot mark" means an identifying mark or other identifying device assigned to a master lot by the manufacturer thereof.

(j) The term "batch mark" means an identifying mark or other identifying device assigned to a batch by the manufacturer thereof.

(k) The term "Secretary" means the Secretary of Health, Education, and Welfare.

(l) The term "Commissioner" means the Commissioner of Food and Drugs.

(m) The functions and duties of the Commissioner under the regulations in this part may be exercised by such other responsible officials of the Food and Drug Administration as the Commissioner may designate for that purpose.

(n) The term "act" means the Federal Food, Drug, and Cosmetic Act, as amended.

(o) The definitions and interpretations of terms contained in section 201 of the act shall be applicable to such terms when used in the regulations in this part.

§ 164.2 *Requests for certification; samples; storage; approvals preliminary to certification.* (a) A request for certification of a batch shall be addressed to the Commissioner, Food and Drug Administration, Department of Health, Education, and Welfare, Washington 25, D. C. A request from a foreign manufacturer shall be signed by such manufacturer and by an agent of such manufacturer who resides in the United States.

(b) The initial request for certification submitted by any person shall be preceded or accompanied by a full statement of the facilities and controls used to maintain the identity, strength, quality, and purity of each batch, including a description of:

(1) The equipment, methods, and processes used in diluting master lots and parts thereof, and in maintaining the identity, strength, quality, and purity of master lots and dilutions therefrom;

(2) The tests and assays made on master lots and mixtures thereof, on dilutions and batches therefrom, and on ingredients used in such dilutions and batches; and

(3) The laboratory facilities used in such controls.

Such initial request shall also be preceded or accompanied by the keys to the master lot marks and batch marks used by such person. When any change is made in any of such facilities or controls, or in any such key, the next request for certification thereafter shall be accompanied by a full statement of such change.

(c) A person who requests certification of a batch shall submit in connection with his request statements showing:

(1) The master lot mark of each master lot used or to be used wholly or partly as an ingredient or component of an ingredient of the batch;

(2) The quantity of each such master lot so used;

(3) The original quantity of each such master lot (unless such information has been previously submitted);

(4) The quantity of the batch; and

(5) The batch mark.

(d) Except as otherwise provided in paragraphs (g) and (h) of this section, a person who requests certification of a batch shall submit in connection with his request and in the quantities hereinafter indicated, accurately representative samples of the following:

(1) The single master lot or the mixture of two or more master lots or parts thereof, to be used as ingredients of the batch; in a quantity containing approximately 10,000 U. S. P. Units of insulin, except that, if the batch is to be isophane insulin, the quantity shall contain not less than 20,000 U. S. P. Units of Insulin.

(2) A trial dilution made from such master lot or mixture, glycerin, phenol or cresol, and hydrochloric acid, which dilution conforms to the standard of identity, strength, quality, and purity for insulin U. S. P., except that it may contain not less than 35 U. S. P. Units nor more than 45 U. S. P. Units of insulin per cubic centimeter; in a quantity containing approximately 2,000 U. S. P. Units of insulin.

(3) If the batch is to be protamine zinc insulin, a trial mixture which is intended to be accurately representative of the mixture which will constitute the finished batch; in a quantity containing approximately 2,000 U. S. P. Units of insulin.

(4) If the batch is to be protamine zinc insulin or isophane insulin, the lot of protamine used as an ingredient of the trial mixture referred to in subparagraph (3) or (7) of this paragraph; in a quantity of approximately 2 grams.

(5) If the batch is to be globin zinc insulin, a trial mixture made from the master lot or mixture referred to in subparagraph (1) of this paragraph, globin, zinc chloride, hydrochloric acid, glycerin, and phenol or cresol, which mixture is intended to be accurately representative of the mixture which will constitute the finished batch; in a quantity containing approximately 2,000 U. S. P. Units of insulin.

(6) If the batch is to be globin zinc insulin, the lot of globin hydrochloride from which the globin is to be prepared for use as an ingredient of the trial mixture referred to in subparagraph (5) of this paragraph; in a quantity of approximately 5 grams.

(7) If the batch is to be isophane insulin, a trial mixture which is intended to be accurately representative of the finished batch; in a quantity of approximately 2,500 U. S. P. Units of insulin.

(8) If the batch is to be lente insulin, a trial mixture which is intended to be accurately representative of the finished batch; in a quantity of approximately 50 milliliters.

(9) The finished batch; in a quantity not less than five packages; except that if the batch is insulin U. S. P. of 500-unit strength; in a quantity of one package.

(e) Except as otherwise provided by paragraphs (g) and (h) of this section, a person who requests certification shall submit in connection with his request results of the tests and assays listed after each of the following materials, made by him on a sample of such material:

(1) The master lot or mixture, referred to in paragraph (d) (1) of this section: Ash, nitrogen, potency, reaction, sterility, and zinc, if such master lot or mixture is a solution; ash, moisture, nitrogen, potency, and zinc, if such master lot or mixture is a solid.

(2) A trial dilution of such master lot or mixture, of the potency of the trial dilution referred to in paragraph (d) (2) of this section: Nitrogen, reaction, and potency.

(3) If the batch is to be protamine zinc insulin, the trial mixture referred to in paragraph (d) (3) of this section: Nitrogen, reaction, zinc, and biological reaction (by the test prescribed in the official United States Pharmacopeia, including supplements thereto).

(4) If the batch is to be protamine zinc insulin or isophane insulin, the protamine referred to in paragraph (d) (4) of this section: Moisture, nitrogen, and sulfate.

(5) If the batch is to be globin zinc insulin, the trial mixture referred to in paragraph (d) (5) of this section: Nitrogen, reaction, zinc, and biological reaction (by the test prescribed in the official United States Pharmacopeia, including supplements thereto).

(6) If the batch is to be globin zinc insulin, the globin hydrochloride referred to in paragraph (d) (6) of this section: Moisture, nitrogen, chloride, and ash.

(7) If the batch is to be isophane insulin, the trial mixture referred to in paragraph (d) (7) of this section: Nitrogen, reaction, zinc, isophane ratio of the protamine to the master lot or mixture (by the test prescribed in § 164.14 (c)), and biological activity of the supernatant liquid (by the test prescribed in the official United States Pharmacopeia, including supplements thereto).

(8) If the batch is to be lente insulin, the trial mixture referred to in paragraph (d) (8) of this section: Nitrogen, reaction, zinc, zinc in the supernatant liquid, and proportion of crystalline component (by the test prescribed in § 164.14 (e)).

(9) The finished batch: Nitrogen, reaction, sterility; and if the batch is protamine zinc insulin, globin zinc insulin, isophane insulin, or lente insulin, zinc.

(f) The results of tests and assays for the following shall be reported in the terms indicated:

(1) Ash (except globin hydrochloride)—milligrams per 1,000 U. S. P. Units of insulin.

(2) Ash in globin hydrochloride—percent by weight.

(3) Chloride—percent by weight as HCl.

(4) Isophane ratio—milligrams of protamine per 100 U. S. P. Units of insulin.

(5) Moisture—percent by weight.

(6) Nitrogen (except in globin hydrochloride and protamine)—milligrams per milliliter in the cases of solutions and suspensions, and percent by weight in the case of solids.

(7) Nitrogen in globin hydrochloride—percent by weight, calculated to a moisture-free, ash-free, chloride-free basis.

(8) Nitrogen in protamine—percent by weight, calculated to a moisture-free basis.

(9) Potency—U. S. P. Units of insulin per milliliter in the case of solutions, and U. S. P. Units of insulin per milligram in the case of solids.

(10) Proportion of crystalline component—percent of total nitrogen of the preparation present in the crystalline component.

(11) Reaction—hydrogen ion concentration (pH).

(12) Sulfate—percent by weight, as SO_4, calculated to a moisture-free basis.

(13) Zinc—milligrams per milliliter in the cases of solutions and suspensions, and percent by weight in the case of solids.

(g) (1) No sample referred to in paragraph (d) (1) to (8), inclusive, of this section, and no result referred to in paragraph (e) (1) to (8), inclusive, of this section, is required if such sample or result has been submitted in connection with a previous request for certification. No sample referred to in paragraph (d) (3) of this section, and no result referred to in paragraph (e) (3) of this section, is required if the batch is to be protamine zinc insulin of 80-unit strength and the Commissioner has previously approved a trial mixture referred to in paragraph (d) (3) of this section of 40-unit strength, prepared from the same materials and in the same manner (except for adjustment of reaction of the buffer solution) as such batch of 80-unit strength is to be made. No sample referred to in paragraph (d) (5) of this section and no result referred to in paragraph (e) (5) of this section, is required if the batch is to be globin zinc insulin of 80-unit strength and the Commissioner has previously approved a trial mixture referred to in paragraph (d) (5) of this section of 40-unit strength, prepared from the same materials and in the same manner as such batch of 80-unit strength is to be made. No sample referred to in paragraph (d) (7) of this section, and no result referred to in paragraph (e) (7) of this section, is required if the batch is to be isophane insulin of 80-unit strength and the Commissioner has previously approved a trial mixture referred to in paragraph (d) (7) of this section of 40-unit strength, prepared from the same materials and in the same manner as such batch of 80-unit strength is to be made.

(2) Each sample submitted pursuant to this section shall be so packaged as to maintain its representative character, and in the case of any solution or suspension, shall be collected and packaged under aseptic conditions. Each package shall be clearly identified as to its contents and shall bear the name and post office address of the person submitting the request.

(3) The packages constituting the samples submitted pursuant to paragraph (d) (9) of this section shall be collected at such intervals that the quantities packaged between collections are approximately equal; in no case shall any such quantity be more than 10,000 packages. The collections shall cover the entire period of packaging.

(4) Each sample submitted pursuant to paragraph (d) (2), (3), (5), (7) and (8) of this section shall be accompanied by a statement showing the identity, quality, and quantity of each substance used as an ingredient or as a component of an ingredient in the material from which the sample was taken.

(5) If the tests and assays, results of which are submitted pursuant to paragraph (e) (2) of this section, were not made on the same trial dilution as that from which the sample submitted pursuant to paragraph (d) (2) of this section was taken, such sample shall be accompanied by a statement showing the identity, quality, and quantity of each substance used as an ingredient or as a component of an ingredient of the trial dilution on which such tests and assays were made.

(6) The value for nitrogen submitted pursuant to paragraph (e) (1) and (2) of this section may be calculated from the result of a test therefor submitted pursuant to either paragraph (e) (1) or (2) of this section. The result on potency required under paragraph (e) (1) of this section may be calculated from an assay therefor submitted pursuant to paragraph (e) (2) of this section. The value of each of the components nitrogen and zinc, to the extent required under paragraph (e) (9) of this section, may be calculated from the result of a test therefor submitted pursuant to paragraph (e) (3), or (5), or (7), or (8) of this section or from the result of a test of the bulk dilution from which the batch was prepared. The value for nitrogen required under paragraph (e) (9) of this section may, if the batch is insulin U. S. P. or lente insulin, be calculated from a test therefor submitted pursuant to either paragraph (e) (1) or (2) of this section. Each calculated value shall be indicated as such.

(7) The information required under paragraph (c) (1), (2), and (3) of this section, and the samples and results of tests and assays required under paragraphs (d) (1) and (2) and (e) (1) and (2) of this section, should be submitted before submission of the samples and results required in paragraph (d) (3) to (8), inclusive, of this section and (e) (3) to (8), inclusive, of this section; and the samples and results required under paragraphs (d) (3) to (8), inclusive, and (e) (3) to (8), inclusive, should be submitted before submission of the information, samples, and results required under paragraphs (c) (4) and (5), (d) (9) and (e) (9) of this section. All information, including results of tests and assays (except results of tests for sterility), required under this section should be submitted at the same time as the samples to which they relate are submitted.

(h) The person who requests certifications shall submit such information additional to that submitted pursuant to paragraphs (b), (c), (e), and (g) of this section, such additional samples of any substance referred to in paragraph (d) of this section, and such samples of any other substance used or to be used as an ingredient or as a component of an ingredient in the batch, as the Commissioner may require for the purpose of investigations to determine whether or not such batch complies with the requirements set forth by § 164.3 for the issuance of a certificate.

(i) After a sample required by paragraph (d) of this section is taken from any master lot or mixture of parts of two or more master lots, such master lot or master lots and all parts thereof, and all dilutions and batches and all parts thereof in which any such master lot is used as an ingredient or as a component of an ingredient, shall be stored at the establishment where manufactured until used up or shipped or otherwise delivered, at a temperature above freezing but not above 15° C. (59° F.), and under such other conditions as prevent, so far as practicable, any change in composition; except that master lots and parts thereof which are solids may be stored at ordinary room temperatures.

(j) As promptly as practicable after the samples submitted pursuant to paragraph (d) (1) and (2) of this section, and any other material or information relative thereto that may be required under this section, are received by the Commissioner, he shall notify the person who submitted such samples of his approval or refusal to approve the use of the master lot or mixture for the making of bulk dilutions. In case of a refusal to approve, the Commissioner shall state his reasons therefor.

(k) In like manner, the Commissioner shall notify the person who submits samples pursuant to paragraph (d) (3) to (8), inclusive, of this section of his approval or refusal to approve the use of the materials represented by such samples in completing the manufacture of the batch. In case of a refusal to approve, the Commissioner shall state his reasons therefor.

(l) If, under the provisions of paragraph (j) or (k) of this section, the Commissioner has refused to approve any material for use in a subsequent operation, he shall examine no other sample required hereunder which includes such material as an ingredient or component of an ingredient, unless and until the person requesting certification makes an adequate showing that the cause for such refusal no longer exists.

§ 164.3 *Certifications.* (a) If it appears to the Commissioner, after such investigation as he considers necessary, that:

(1) The information (including results of tests and assays) and the samples required by or pursuant to § 164.2 have been submitted, and such information contains no untrue statement of a material fact;

(2) The batch complies with these regulations and conforms to the standards of identity, strength, quality, and purity for insulin U. S. P., protamine zinc insulin, globin zinc insulin, isophane insulin, or lente insulin;

the Commissioner shall certify that such batch is safe and efficacious for use, subject to such conditions on the effectiveness of such certifications as are set forth in § 164.4, and shall issue to the person who requested it a certificate to that effect.

(b) If the Commissioner determines, after such investigation as he considers to be necessary, that the information submitted pursuant to § 164.2, or the batch covered by such request, does not comply with the requirements set forth in paragraph (a) of this section for the issuance of a certificate, the Commissioner shall refuse to certify such batch and shall give notice thereof to the person who requested certification, stating his reasons for refusal.

(c) For the purposes of his investigations under the authority of this section, the Commissioner may accept, when he is satisfied as to the completeness and accuracy thereof, the results of any tests or assays made by the control laboratory of the Insulin Committee of the University of Toronto.

§ 164.4 *Conditions on the effectiveness of certificates.* (a) A certificate shall not become effective:

(1) If it is obtained through fraud, or through misrepresentation or concealment of a material fact;

(2) With respect to any package, unless its immediate container complies with the requirements of § 164.5 and such package or such immediate container has been so sealed that its contents cannot be used without destroying such package or seal; or

(3) With respect to any package, unless its label and labeling bear all words, statements, and other information, and are distinguished by the color or colors, required by §§ 164.6 and 164.7.

(b) A certificate shall cease to be effective:

(1) With respect to any package of insulin U. S. P., protamine zinc insulin, globin zinc insulin, or isophane insulin, on the expiration date specified in the official United States Pharmacopeia, including supplements thereto;

(2) With respect to any package of lente insulin, 18 months after the immediate container therein was filled;

(3) With respect to any package, when such package or the seal thereof or the immediate container therein or the seal of the immediate container is broken, or when its label or labeling ceases to conform to any requirement of § 164.6 or § 164.7; or

(4) With respect to any package, when the drug therein so changes that it fails to meet the standards of identity, strength, quality, and purity upon the basis of which the batch was certified; except that those minor changes in potency (not exceeding 10 percent from the potency stated on the label, in the case of insulin U. S. P.) which occur before the expiration date, and which are normal and unavoidable in good storage and distribution practice, shall be disregarded.

§ 164.5 *Packaging.* Each batch shall be packaged in immediate containers of colorless transparent glass. Such containers shall be closed with a substance through which successive doses may be withdrawn by hypodermic needle without removing the closure or destroying its effectiveness. The containers and closures shall be sterile at the time the containers are filled and closed. The composition of the containers and closures shall be such as will not cause any change in the strength, quality, or purity of the contents beyond any limit therefor prescribed in applicable standards of strength, quality, and purity. The shape of the containers shall be cylindrical, except that the cross-section of the containers for isophane insulin shall be a rounded square and the shoulder of the containers for lente insulin shall be hexagonal.

§ 164.6 *Labeling.* Each package from a batch that has been certified in accordance with the regulations in this part shall bear, on its label or labeling as hereinafter indicated, the following:

(a) On the outside wrapper or container and the immediate container of the retail package:

(1) The batch mark of such batch;

(2) The strength of the drug in terms of the U. S. P. Units of insulin per milliliter; and

(3) If the seal required by § 164.4 (a) (2) is on the immediate container only, the statement required by paragraph (b) (1) of this section.

(b) On the outside container or wrapper of the retail package:

(1) The statement "Expiration date ______," the blank being filled in with the date on which the certificate applicable to such batch expires with respect to such package, as provided in § 164.4 (b) (1) or (2); and

(2) The statement "Keep in a cold place, avoid freezing."

(c) If the batch contains 40, 80, or 100 U. S. P. Units of insulin per milliliter, on the circular or other labeling of the retail package:

(1) A statement that the treatment of diabetes mellitus is an individual problem and that the use of the drug, the time of its administration, and the number of daily doses and the quantity of each, as well as diet and exercise, are problems which require direct and continuous medical supervision;

(2) A statement explaining that the volume of the dose depends on the number of units of insulin per milliliter stated on the label, and that the patient should understand the meaning of the volume markings on the syringe;

(3) A description of a practicable method for sterilizing the needle and syringe before use;

(4) A description of the technique of withdrawal from the vial and the use of an antiseptic on the stopper, and a caution against the removal of the stopper;

(5) A description of the technique for cleansing, and the use of an antiseptic on the site of injection;

(6) A statement that failure to comply with the techniques described in subparagraphs (3), (4), and (5) of this paragraph may lead to infection of the patient;

(7) A statement that injection should be subcutaneous, at a different site from that of the preceding injection, and a caution against intravenous or intramuscular use;

(8) An explanation of hypoglycemia and its relation to overdosage, omission of meals, illness, and infection;

(9) A statement of the significance of sugar in the urine and of the necessity of tests therefor; and

(10) A caution against use after the expiration date shown on the outside wrapper or container.

(d) On the circular or other labeling of the retail package, if the batch is insulin U. S. P. (in addition to the information required by paragraphs (a), (b), and (c) or (i) of this section), a caution against use if the drug has become viscous or if its color has become other than water clear.

(e) On the outside wrapper or container and the immediate container of the retail package, if the batch is protamine zinc insulin, isophane insulin, or lente insulin (in addition to the information required by paragraphs (a), (b), and (c) of this section), the statement "Shake carefully," or "Shake well before using," or "Shake well," or "Shake carefully to suspend all particles."

(f) On the circular or other labeling of the retail package, if the batch is protamine zinc insulin, isophane insulin, or lente insulin (in addition to the information required by paragraphs (a), (b), (c), and (e) of this section):

(1) An explanation of the difference, as compared with other insulin-containing drugs, in onset of action, duration, and the time and frequency of administration;

(2) A caution that it is not to be substituted for any other insulin-containing drug except on the advice and direction of a physician;

(3) A statement that a uniform suspension of the preparation is necessary and is brought about by careful shaking before use; and

(4) A caution against use when the precipitate has become lumped or granular in appearance or has formed a deposit of solid particles on the wall of the container.

(g) On the circular or other labeling of the retail package, if the batch is globin zinc insulin (in addition to the information required by paragraphs (a), (b), and (c) of this section):

(1) An explanation of the difference, as compared with other insulin-containing drugs, in onset of action, duration, and the time and frequency of administration;

(2) A caution that it is not to be substituted for any other insulin-containing drug, except on the advice and direction of a physician; and

(3) A caution against use if any turbidity or precipitate has developed in the solution.

(h) If the batch contains 500 U. S. P. Units of insulin per milliliter, on the outside container or wrapper and the immediate container of the retail package:

(1) The statement "Caution: Federal law prohibits dispensing without prescription"; and

(2) The statement "Warning—High potency—Not for ordinary use."

(i) If the batch contains 500 U. S. P. Units of insulin per milliliter, on the circular or other labeling of the retail package:

(1) Information adequate for the safe and effective use of the drug, by practitioners licensed by law to administer it, in insulin shock therapy and for the treatment of diabetic patients with high insulin resistance (daily requirement more than 200 units);

(2) A prominently placed and conspicuous statement: "Warning—This insulin preparation contains 500 units of insulin in each cubic centimeter. Extreme caution must be observed in measurement of dosage because inadvertent overdose may result in irreversible insulin shock. Serious consequences may result if it is used other than under constant medical supervision";

(3) A caution against intravenous use; and

(4) A caution against use after the expiration date shown on the outside wrapper or container.

§ 164.7 *Distinguishing colors on packages.* (a) The outside containers or wrappers of the packages, and the labels on the immediate containers, of each strength of insulin U. S. P. shall be distinguished by the following colors:

Red, if it contains 40 U. S. P. Units of insulin per milliliter.

Green, if it contains 80 U. S. P. Units of insulin per milliliter.

Orange, if it contains 100 U. S. P. Units of insulin per milliliter.

Narrow (at least 5 but not more than 20 to each inch) brown and white diagonal stripes, if it contains 500 U. S. P. Units of insulin per milliliter.

But if the master lot used was in crystalline form, the distinguishing colors, instead of those prescribed above, may be the following:

Red and gray, if it contains 40 U. S. P. Units of insulin per milliliter.

Green and gray, if it contains 80 U. S. P. Units of insulin per milliliter.

(b) The outside containers or wrappers of the packages, and the labels on the immediate containers, of each strength of protamine zinc insulin shall be distinguished by the following colors:

Red and white, if it contains 40 U. S. P. Units of insulin per milliliter.

Green and white, if it contains 80 U. S. P. Units of insulin per milliliter.

(c) The outside containers or wrappers of the packages, and the labels of the immediate containers, of each strength of globin zinc insulin shall be distinguished by the following colors:

Red and brown, if it contains 40 U. S. P. Units of insulin per milliliter.

Green and brown, if it contains 80 U. S. P. Units of insulin per milliliter.

(d) The outside containers or wrappers of the packages, and the labels of the immediate containers, of each strength of isophane insulin shall be distinguished by the following colors:

Red and blue, if it contains 40 U. S. P. Units of insulin per milliliter.

Green and blue, if it contains 80 U. S. P. Units of insulin per milliliter.

(e) The outside containers or wrappers of the packages, and the labels of the immediate containers, of each strength of lente insulin shall be distinguished by the following colors:

Red and lavender, if it contains 40 U. S. P. Units of insulin per milliliter.

Green and lavender, if it contains 80 U. S. P. Units of insulin per milliliter.

§ 164.8 *Records of distribution.* (a) The person to whom a certificate is issued shall keep complete records showing each shipment and other delivery (including exports) of each batch or part thereof, by the person requesting certification, and showing each such shipment and delivery into, or from any place in, any State or Territory, made by any person subject to his control, including records showing the date and quantity of each such shipment and delivery and the name and post office address of the person to whom such shipment or delivery was made.

(b) Upon the request of any officer or employee of the Food and Drug Administration or of any other officer or employee of the United States, acting on behalf of the Secretary, the person to whom a certificate is issued, at all reasonable hours within 3 years after disposal of all the batch covered by such certificate, shall make such records available to any such officer or employee, and shall accord to such officer or employee full opportunity to make inventory of stocks of such batch on hand and otherwise to check the correctness of such records.

§ 164.9 *Authority to refuse certification service.* When the Secretary finds, after giving notice and opportunity for hearing, that a person has:

(a) Obtained or attempted to obtain a certificate through fraud, or through misrepresentation or concealment of a material fact;

(b) Falsified the records required to be kept by § 164.8; or

(c) Failed to keep such records or to make them available, or to accord full opportunity to make an inventory of stocks on hand or otherwise to check the correctness of such records, as required by such section,

the Secretary may immediately suspend service to such person under the regulations in this part, and may continue such suspension unless and until such person shows adequate cause why such suspension should be terminated.

§ 164.10 *Fees.* (a) (1) Fees for the services rendered under the regulations in this part shall be such as are necessary to provide, equip, and maintain an adequate certification service.

(2) Whenever in the judgment of the Commissioner the ratio between fees collected (which are based upon experience and the best estimate of costs and the best estimate of earnings) and the costs of providing the service during an elapsed period of time, in the light of all circumstances and contingencies, warrants a refund from the fund collected during such period, he shall make ratable refunds to those persons to whom the services were rendered and charged, except for those services described under paragraph (b) (2) (ii), (3) (ii), and (5) of this section.

(b) The fees for the services rendered with respect to the samples submitted pursuant to § 164.2 (d) shall be:

(1) For each master lot or mixture of two or more master lots or parts thereof, as follows:

(i) $50 if the master lot or mixture has not been previously approved by the Commissioner;

(ii) $25 if the master lot or mixture has been previously approved by the Commissioner in accordance with § 164.2 (j).

(2) For each trial dilution, as follows:

(i) $50 if the results of an assay for potency of a trial dilution made by the laboratory referred to in § 164.3 (c) are submitted or are to be submitted;

(ii) The cost of the services rendered if the results referred to in subdivision (i) of this subparagraph are not submitted and are not to be submitted.

(3) For each trial mixture of protamine zinc insulin, as follows:

(i) $50 if the results of tests for biological reactions made by the laboratory referred to in § 164.3 (c) are submitted or are to be submitted;

(ii) The cost of the services rendered if the results referred to in subdivision (i) of this subparagraph are not submitted and are not to be submitted.

(4) $50 for each lot of protamine.

(5) The cost of the services rendered for each trial mixture of globin zinc insulin, isophane insulin, or lente insulin.

(6) $50 for each lot of globin hydrochloride.

(7) $10 for each package in the sample of the finished batch.

Except as otherwise provided by paragraph (c) of this section, each request for certification submitted, or the initial sample or samples submitted in connection therewith pursuant to § 164.2 (d), whichever is sent first to the Commissioner, shall be accompanied by such fees as are prescribed in specific amounts for the samples submitted. When the fee is the cost of the services rendered, each sample referred to in subparagraph (2) (ii) of this paragraph shall be accompanied by an advance deposit of $1,200; each sample referred to in subparagraphs (3) (ii) and (5) of this paragraph shall be accompanied by an advance deposit of $500; and thereafter such additional advance deposits shall be made as the Commissioner estimates may be necessary to prevent arrears in the payment of such fee.

(c) A person requiring continuing certification services may maintain an advance deposit of the estimated costs of such services for a period of 2 months or more. Such deposits shall be debited with fees for services rendered, but shall not be debited for any fee the amount of which is not definitely specified in these regulations unless the depositor has previously requested the performance of the services to be covered by such fee. A monthly statement for each such advance deposit shall be rendered.

(d) The unearned portion of any advance deposit made pursuant to paragraph (b) or (c) of this section shall be refunded to the depositor upon his application.

(e) All advance deposits required by the regulations in this part shall be paid by money order, bank draft, or certified check drawn to the order of the Treasurer of the United States, collectible at par at Washington, D. C. All deposits shall be forwarded to the Food and Drug Administration, Department of Health, Education, and Welfare, Washington 25, D. C., whereupon after making appropriate record thereof they will be transmitted to the Chief Disbursing Officer, Division of Disbursement, Treasury Department, for deposit to the special account "Certification and Inspection Services, Food and Drug Administration."

§ 164.11 *Standards of quality and purity for protamine.* When protamine is dried to constant weight at 100° C., its total nitrogen content is not less than 22.5 percent and not more than 25.5 percent, and its sulfate content, calculated as SO_4, is not less than 16 percent and not more than 19 percent.

§ 164.12 *Standards of quality and purity for globin hydrochloride.* The ash content of globin hydrochloride is not more than 0.3 percent; its nitrogen content, calculated to moisture, ash, and hydrochloric acid free basis, is not less than 16.0 percent and not more than 17.5 percent.

§ 164.13 *Standards of identity, strength, quality, and purity for lente insulin.* Lente insulin is a sterile suspension, in a buffered water medium, of insulin modified by the addition of zinc chloride. Of the insulin contained in the preparation not more than 1 U. S. P. Unit of insulin per milliliter is in solution, approximately 70 percent is crystalline, and the remainder is amorphous. Zinc-insulin crystals are used in such quantity that each milliliter of the preparation, when the precipitate therein is brought into uniform suspension, contains either 40 or 80 U. S. P. Units of insulin. The preparation contains, for each 100 U. S. P. Units of insulin, not less than 0.20 milligram and not more than 0.25 milligram zinc (of which not less than 40 percent nor more than 65 percent is in the supernatant liquid), and not more than 0.65 milligram nitrogen. The preparation also contains not less than 0.15 percent and not more than 0.17 percent (w/v) sodium acetate, not less than 0.65 percent and not more than 0.75 percent (w/v) sodium chloride, and not less than 0.09 percent and not more than 0.11 percent (w/v) methyl-*p*-hydroxybenzoate. The pH of the finished product is not less than 7.1 nor more than 7.5.

§ 164.14 *Tests and methods of assay.* The following tests and methods of assay are prescribed for the purposes of the regulations in this part. (All reagents specified in this section shall be of U. S. P. quality or better.)

(a) *Tests and methods of assay for insulin U. S. P., protamine zinc insulin, globin zinc insulin, and isophane insulin.* The tests and methods of assay for insulin U. S. P., protamine zinc insulin, globin zinc insulin, and isophane insulin shall be those set forth therefor in the official United States Pharmacopeia, including supplements thereto.

(b) *Identification of lente insulin.* Acidify lente insulin to a pH between 2.5 and 3.5. The precipitate dissolves, giving a clear, colorless liquid which conforms to the requirements of the identification test for insulin U. S. P. in the official United States Pharmacopeia, including supplements thereto. Add a few drops of ferric chloride test solution to lente insulin. A reddish-brown color develops that is destroyed by the addition of a mineral acid.

(c) *Isophane ratio.* The isophane ratio shall be expressed as milligrams of protamine per 100 U. S. P. Units of Insulin.

(1) *Reagents*—(i) *The stock buffer solution.* Dissolve in water the quantities of metacresol, phenol, glycerin, and disodium phosphate required to make 10 liters of the batch of isophane insulin and dilute to 1,000 milliliters.

(ii) *The insulin solution.* From a sample of the zinc-insulin crystals to be used in making the batch weigh a quantity which contains 10,000 U. S. P. Units of insulin. Dissolve the crystals in 15 milliliters of 0.1 percent hydrochloric acid. The resulting solution must be clear. Add it to 25 milliliters of the stock buffer solution (subdivision (i) of this subparagraph). Dilute with water to approximately 200 milliliters. Adjust the pH to 7.2 using hydrochloric acid or sodium hydroxide. The solution must be clear at this stage. If sodium chloride is to be used in preparing the batch add 25 milliliters of 4.2 percent (w/v) sodium chloride solution. Dilute to 250 milliliters with water. The pH must be between 7.1 and 7.4.

(iii) *The protamine solution.* Weigh 500 milligrams of the protamine to be used in making the batch and dissolve in 10 milliliters of the stock buffer solution (subdivision (i) of this subparagraph). If sodium chloride is to be used in preparing the batch add 10 milliliters of 4.2 percent (w/v) sodium chloride solution. Dilute with water to approximately 80 milliliters. Adjust the pH to 7.2 using hydrochloric acid or sodium hydroxide. Dilute with water to 100 milliliters. The pH must be between 7.2 and 7.4, and the solution must be clear.

(2) *Conduct of the test.* Measure six 25-milliliter samples of the insulin solution (subparagraph (1) (ii) of this paragraph) into six tubes. To the first tube add 0.60 milliliter of the protamine solution (subparagraph (1) (iii) of this paragraph), to the second add 0.72 milliliter, to the third add 0.84 milliliter, to the fourth add 0.96 milliliter, to the fifth add 1.08 milliliters, and to the sixth add 1.20 milliliters. Mix the contents of each tube and let stand for at least 30 minutes. Centrifuge. (Do not filter.) From each supernatant fluid remove two 10-milliliter samples, thus creating two series of samples. To each of one series add 1 milliliter of the insulin solution (subparagraph (1) (ii) of this paragraph). To each of the other series add 1 milliliter of the protamine solution (subparagraph (1) (iii) of this paragraph). Mix each sample and let stand 10 minutes. Measure the turbidity of each sample by means of a photometer or nephelometer. Plot the readings of the two series of samples, using the amount of protamine originally added in milligrams per 100 U. S. P. Units of insulin as abscissas, and the photometer or nephelometer readings as ordinates. The abscissa of the intersection of the two curves indicates the isophane ratio of the protamine to the zinc-insulin crystals. In order to increase the precision of the test, when the approximate isophane ratio is known, the quantities of protamine solution to be added to the six tubes may be so chosen that the range (0.60 to 1.20 milliliters) is reduced, and the approximate isophane ratio is near the middle of the range.

The isophane ratio found is not more than 100 percent nor less than 90 percent of the ratio of protamine to insulin used in the trial mixture referred to in § 164.2 (d) (7).

(d) *Proportion of crystalline component in lente insulin.* The proportion of crystalline component shall be expressed as percent of the total nitrogen of the preparation which is present in the crystalline component.

(1) *Reagent.* Dissolve in water 8.15 grams of crystalline sodium acetate and 42 grams of sodium chloride. Add 68 milliliters of tenth-normal hydrochloric acid, 150 milliliters of acetone, and sufficient water to make 500 milliliters.

(2) *Conduct of test.* Centrifuge 15 milliliters of lente insulin and carefully pour off the supernatant liquid. Resuspend the solid phase in 5 milliliters of water and 10 milliliters of the wash reagent (subparagraph (1) of this paragraph) and again centrifuge. Discard the supernatant liquid and repeat the washing with the same quantities of water and wash reagent and again discard the supernatant liquid. Dissolve the crystalline residue in sufficient dilute hydrochloric acid to make the volume 15 milliliters. Determine the nitrogen content of this solution by the method specified in paragraph (h) of this section. The nitrogen found must be not less than 55 percent nor more than 67 percent of the total nitrogen of the preparation.

(e) *Sterility of lente insulin.* Use the method described in the official United States Pharmacopeia, including supplements thereto, for insulin U. S. P.

(f) *Chloride in globin hydrochloride*—(1) *Conduct of the test.* Weigh accurately approximately 0.5 gram of globin hydrochloride into a small beaker and dissolve in 10-15 milliliters of distilled water. Add 10 milliliters of tenth-normal silver nitrate, 5 milliliters of nitric acid, and 5 milliliters of a saturated solution of potassium permanganate. Stir and place on a steam bath for approximately 1 hour. If any brown color remains, stir again, rinse the sides of the beaker with distilled water and place on the steam bath until the brown color disappears. Transfer quantitatively to a 50-milliliter volumetric flask and fill the flask to the mark with distilled water. Mix and filter through a dry filter paper into a dry vessel. Transfer exactly 40 milliliters of the filtrate to a flask, add 2 milliliters of ferric ammonium sulfate test solution and titrate with tenth-normal ammonium thiocyanate. To obtain the percent chloride as HCl, subtract 1.25 times the number of milliliters of ammonium thiocyanate used from 10; multiply this difference by 0.365 and divide by the weight of the sample in grams.

(2) *Reagents.* The reagents used are those described in the official United States Pharmacopeia, including supplements thereto.

(g) *Sulfate in protamine*—(1) *Conduct of the test.* Weigh accurately about 250 milligrams of protamine and dissolve it in about 100 milliliters of approximately tenth-normal hydrochloric acid. Heat to boiling and add 5 milliliters of barium chloride test solution. Digest on a steam bath for 1 hour; allow to cool. Filter through an ignited and weighed Gooch crucible; wash free of chlorides. Dry, ignite, and weigh. The weight of barium sulfate thus obtained multiplied by 41.15 and divided by the weight of sample is the percent sulfate (SO_4) in the sample. Calculate the results to a moisture-free basis.

(2) *Reagents.* The reagents used are those described in the official United States Pharmacopeia, including supplements thereto.

(h) *Nitrogen.* Determine total nitrogen by the method described in the official United States Pharmacopeia, including supplements thereto, for insulin U. S. P.

(i) *Zinc in insulin-containing solutions or suspensions.* Use the method described in the official United States Pharmacopeia, including supplements thereto, for insulin U. S. P.

(j) *Zinc in insulin-containing solids.* Dissolve 10 to 20 milligrams, accurately weighed, of insulin-containing solids in 5 to 10 milliliters of distilled water containing 1 drop of five-normal hydrochloric acid, and proceed as directed in the official United States Pharmacopeia, including supplements thereto, under the test for zinc in insulin U. S. P.

PART 165—CERTAIN CHEMICAL DERIVATIVES OF SUBSTANCES NAMED IN SECTION 502 (d) OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT DESIGNATED AS HABIT FORMING

§ 165.1 *Habit-forming drugs which are chemical derivatives of substances specified in section 502 (d) of the Federal Food, Drug, and Cosmetic Act.* Each of the following chemical derivatives of a substance named in section 502 (d) of the Federal Food, Drug and Cosmetic Act is hereby designated as habit forming:

Parent substance	Chemical derivative	Chemical description of derivative
Barbituric Acid	Alurate	(5-allyl-5-isopropyl-barbituric acid.)
	Amytal	(5-ethyl-5-isoamyl-barbituric acid.)
	Barbital	(5,5-diethyl-barbituric acid.)
	Butisol	(5-ethyl-5-*sec*-butyl-barbituric acid.)
	Cyclopal, cyclopen	(5-allyl-5-cyclopantenyl-barbituric acid.)
	Delvinal	(5-ethyl-5-(1-methyl-1-butenyl)-barbituric acid.)
	Dial	(5,5-diallyl-barbituric acid.)
	Eldoral	(5-ethyl-5-(1-piperidyl)-barbituric acid.)
	Eunarcon	(5-(2-bromoallyl)-5-isopropyl-1-methyl-barbituric acid.)
	Evipal	(1,5-dimethyl-5-(1-cyclohexenyl)-barbituric acid.)
	Ipral	(5-ethyl-5-isopropyl-barbituric acid.)
	Mebaral	(5-ethyl-5-phenyl-1-methyl-barbituric acid.)
	Narconumal	(5-allyl-5-isopropyl-1-methyl-barbituric acid.)
	Neonal	(5-ethyl-5-butyl-barbituric acid.)
	Nostal	(5-isopropyl-5-(2-bromoallyl)-barbituric acid.)
	Ortal	(5-ethyl-5-hexyl-barbituric acid.)
	Pentenal	(5-ethyl-5-cyclopentenyl-barbituric acid.)
	Pentobarbital	(5-ethyl-5-(1-methylbutyl)-barbituric acid.)
	Pentothal	(5-ethyl-5-(1-methylbutyl)-2-thio-barbituric acid.)
	Pernoston	(5-*sec*-butyl-5-(2-bromoallyl)-barbituric acid.)
	Phanodorn	(5-ethyl-5-(1-cyclohexenyl)-barbituric acid.)
	Phenobarbital	(5-ethyl-5-phenyl-barbituric acid.)
	Proponal	(5,5-dipropyl-barbituric acid.)
	Rutonal	(5-methyl-5-phenyl-barbituric acid.)
	Sandoptal	(5-allyl-5-isobutyl-barbituric acid.)
	Sigmodal, Rectidon	(5-(2-bromoallyl)-5-(1-methylbutyl)-barbituric acid.)
	All lithium, sodium, potassium, magnesium, calcium, strontium, and ammonium salts of the foregoing chemical derivatives of barbituric acid.	
	Seconal	(sodium-5-allyl-5-(1-methylbutyl)-barbiturate.)
	All salts of the foregoing chemical derivative formed by replacing the sodium with lithium, potassium, magnesium, calcium, strontium, or ammonium radical.	
Bromal	Bromal Hydrate	(tribromoacetaldehyde hydrate.)
	Brometone	(2-(tribromomethyl)-2-propanol.)
	Bromoform	(tribromomethane.)
Cannabis, Marihuana.	Extract of Cannabis.	
	Fluidextract of Cannabis.	
	Tincture of Cannabis.	
Carbromal	Acetylcarbromal	(α-bromo-α-ethylbutyryl-acetyl-urea.)
	Bromural	(α-bromoisovaleryl-urea.)
	Neuronal	(α-bromo-α,α-diethyl-acetamide.)
	Sedormid	(α-allylisovaleryl-urea.)
Chloral	Alpha-Chloralose	(α-(β-trichloro-α-hydroxyethyl)-d-glucoside.)
	Chloralformamide	(N-(β-trichloro-α-hydroxyethyl)-formamide.)
	Chloral Hydrate	(trichloroacetaldehyde hydrate.)
	Chloralimide	(trichloroethylideneimine.)
	Chlorobutanol	(2-(trichloromethyl)-2-propanol.)
Cocaine	All salts of cocaine obtained by combining cocaine with any acid.	
Codeine	Dicodid	(dihydro-codeinone.)
	Eucodal	(dihydrohydroxy-codeinone.)
	All salts of the foregoing chemical derivatives of codeine, and all salts of codeine, obtained by combining any such derivative or codeine with any acid.	
	Eucodin	(codeine methyl bromide.)
Heroin	All salts of heroin obtained by combining heroin with any acid.	
Morphine	Dilaudid	(dihydro-morphinone.)
	Ethylmorphine	
	Paramorphan	(dihydro-morphine.)
	All salts of the foregoing chemical derivatives of morphine, and all salts of morphine, obtained by combining any such derivative or morphine with any acid.	
Opium	Extract of Opium.	
	Fluidextract of Opium.	
	Tincture of Opium.	
Paraldehyde	Metaldehyde.	
Sulphonmethane	Sulfonethylmethane	(2,2-diethylsulfonyl-butane.)
	Sulfondiethylmethane	(3,3-diethylsulfonyl-pentane.)

(Sec. 701 (a), 52 Stat. 1055; 21 U. S. C. 371 (a). Interprets or applies sec. 502 (d), 52 Stat. 1050, as amended; 21 U. S. C. 352 (d))

Subchapter D—[Reserved]

Subchapter E—Regulations Under Specific Acts of Congress Other Than the Food, Drug and Cosmetic Act

PART 281—ENFORCEMENT OF THE TEA IMPORTATION ACT

Sec.
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281.43 Duties of supervising tea examiner.

AUTHORITY: §§ 281.1 to 281.43 issued under sec. 10, 29 Stat. 607, as amended; 21 U. S. C. 50. Interpret or apply sec. 1, 29 Stat. 604, as amended; 21 U. S. C. 41.

CROSS REFERENCE: For Bureau of Customs regulations governing importation of tea, see 19 CFR 12.33.

§ 281.1 *Importation of inferior goods prohibited.* The importation of any merchandise as tea which is inferior in purity, quality, and fitness for consumption to the standards fixed and established by the Secretary of Health, Education, and Welfare, in accordance with section 3 of the Tea Importation Act (29 Stat. 605; 21 U. S. C. 43), is prohibited.

§ 281.2 *Importation without appraisement.* Importations of tea may be entered for consumption, for transit to foreign countries, or for immediate transportation without appraisement. All entries must be on the regular forms, and the regular serial numbers, for both bonds and entries should be used.

§ 281.3 *Bonding of tea for consumption.* Tea entered for consumption must be stored as provided in § 281.5, pending examination, and bond must be taken by the collector of customs, as provided in section 4 of the Tea Importation Act (29 Stat. 605; 21 U. S. C. 44), on Customs Form No. 7551 or 7553. This bond shall be canceled upon the issuance of a permit for release, as the consumption entry bond includes provisions for the redelivery, the exportation, the destruction, and the holding of the merchandise for customs examination.

§ 281.4 *Teas destined for interior ports.* Imported teas entered at an exterior port destined for immediate transportation to an interior port shall be forwarded without detention.

§ 281.5 *Warehouses for storage of tea.* (a) Warehouses for the storage of tea will be designated by the collector of customs and the proprietor thereof will be required to give a bond in the form prescribed (Customs Form No. 3581). Teas not stored in such designated warehouses will be placed in general order store or in public store pending examination and release on proper permit. In the absence of proper storage facilities at customhouses, teas may be retained in locked cars as constructive warehouses, under proper supervision, pending examination.

(b) The importer's premises may be designated as warehouses for the storage of tea on the filing of the bond provided for by the regulations in this part, but whenever, in the discretion of the collector of customs, it shall be considered desirable, a storekeeper shall be assigned to the supervision of such premises at the importer's expense while the teas shall remain under bond therein.

§ 281.6 *Method of storing in warehouse.* (a) When tea under examination is stored in any warehouse it must be so placed as to be separate from other merchandise and so as to allow convenient supervision by customs officers and officers of the Department of Health, Education, and Welfare. At ports where there are no bonded warehouses, class 2 or 3, the chief customs officer of the port will, when necessary, procure suitable premises for the temporary storage of any tea reaching his port. The repacking of tea in warehouse for export purposes is not allowed.

(b) All expenses of storage, cartage, and labor must be paid by the importer.

§ 281.7 *Examination of packages.* Chief officers of customs may order such an examination of packages containing tea as will satisfy them that no dutiable goods are packed therein. For this purpose the customary designation should be made of packages for examination in public store.

§ 281.8 *Tea blended, mixed and repacked for export.* Tea importers desiring to import teas into the United States to be blended, mixed, and repacked for export can do so by bonding a warehouse under the provisions of section 311 of the Tariff Act of 1930 (46 Stat. 691; 19 U. S. C. 1311), upon compliance with §§ 19.13 to 19.15, inclusive, of the Customs Regulation of 1943 (19 CFR 19.13–19.15), giving bond on Customs Form No. 3583. All teas placed in bonded manufacturing warehouses must be exported.

CROSS REFERENCE: For customs regulations governing manufacturing warehouses, see 19 CFR 19.13–19.16.

§ 281.9 *Removal of tea from warehouse.* No tea shall be delivered to the importer or removed from warehouse for any purpose before the examination required by the Tea Importation Act.

§ 281.10 *Exemption of sample packages from examination.* Where tea is put up in packages of not over 2 pounds in weight, imported by mail, express, or otherwise from the country of production, and the fact is established that the packages are samples for distribution, or for use in soliciting orders and not for sale, no examination should be made under the Tea Importation Act (29 Stat. 604; 21 U. S. C. 41–50), and they may be delivered at once to the importer.

§ 281.11 *Tea brought in by passengers.* Packages of tea not exceeding 5 pounds in weight brought by passengers may be delivered without examination under the Tea Importation Act (29 Stat. 604; 21 U. S. C. 41–50).

CROSS REFERENCE: For Bureau of Customs regulations, see 19 CFR 10.17 (d).

§ 281.12 *Unclaimed teas.* Unclaimed teas should be taken possession of by collectors of customs the same as other unclaimed goods and placed in "general order", but not sold at the expiration of the year unless declared fit for consumption by a designated tea examiner.

CROSS REFERENCE: For Bureau of Customs regulations governing disposition of merchandise unclaimed or in warehouse beyond the time fixed by law, see 19 CFR Part 20.

§ 281.13 *Tea packages and contents shall constitute a unit.* Tea packages and contents shall be treated as a unit, and no separation of tea from its covering can be allowed, for either exportation or destruction, except under the two following conditions:

(a) In cases of importations of tea containing an excessive quantity of dust and siftings, the tea may be sifted and admitted to entry if found up to the standard, and the dust and siftings may also be admitted if found up to the standard or, if no standard exists, if found up to the respective leaf standard. If not up to the standard, or respective leaf standard when no standard exists, the dust and siftings must be exported or destroyed under Government supervision.

(b) If, by reason of damage, a tea otherwise equal in quality to the standard has been rejected, the damaged portion may be removed and exported or destroyed under custom's supervision, and the sound remainder resubmitted for examination and admitted to entry if found up to the standard.

§ 281.14 *Taking of samples at ports where tea examiner is stationed.* The examination of teas at ports where a duly qualified tea examiner is stationed shall be made by means of samples drawn by the sampler from packages designated by the tea examiner. The importer, when his teas are ready for sampling, shall submit in duplicate to the tea examiner a chop list and release permit (T. I. S. Cat. No. 1) of the several lines included in the invoice, and the tea examiner shall select for examination packages representing the different lines.

§ 281.15 *Result of examination; form of report.* (a) The examination and report upon such samples shall be made in accordance with the provisions of section 7 of the Tea Importation Act (29 Stat. 606; 21 U. S. C. 46), and the result of this examination shall be noted on the invoice by the tea examiner before he returns the invoice to the collector of customs. The tea examiner at the same time should make his returns on the original copy of the chop list and release permit (T. I. S. Cat. No. 1), which, after being duly signed by him, should be forwarded by him to the importer or consignee.

(b) In case the tea coverings are dutiable and appraised at a value or rate higher than the entered value or rate, the tea examiner shall follow the same procedure as above, except that the chop list and release permit shall be returned to the collector of customs for such action as he sees fit to take.

(c) In case a partial release is desired the importer shall furnish an additional chop list and release permit (T. I. S. Cat. No. 1) of the goods that he desires, the original chop list and release permit being retained by the tea examiner until action on all the teas in the entry has been taken.

§ 281.16 *Taking of samples at ports where there is no tea examiner.* (a) In case an entry of imported tea shall be made at a port or subport where no tea examiner is stationed the importer should prepare the chop list and release permit (T. I. S. Cat. No. 1) in triplicate and forward them to the chief officer of the customs at the port of entry.

(b) Samples shall be obtained by such officers, together with the original and one copy of the chop list and release permit (T. I. S. Cat. No. 1), and shall be forwarded to the nearest qualified tea examiner for his report and return. Samples sent for the purpose of examination from ports of importation to ports where tea examiners are located shall be packed in clean tin cans, free from odor, fitted with tight covers, and of a capacity to hold about 4 ounces avoirdupois of tea. Each can shall be properly labeled (T. I. S. Cat. No. 5).

§ 281.17 *Chop list.* (a) In all cases the importer shall indicate on the chop list and release permit where the goods are to be sampled, whether on the dock or in warehouse. If the consular invoice has not been received the importer may prepare an additional copy of the chop list and release permit as a pro forma invoice, marking across the face thereof "Pro Forma Invoice."

(b) Importers may print their chop list and release permit forms, provided they conform strictly with the official form (T. I. S. Cat. No. 1). Otherwise, they can be obtained free from the United States tea examiner at ports where tea examiners are stationed, or from the chief officer of customs at ports, or subports, where no tea examiners are stationed.

§ 281.18 *Surplus samples.* (a) Surplus samples drawn from importations for purposes of examination, and which represent pure tea as declared by the examiner, shall be returned to the importer after examination is completed, if so requested by the importer, but if no request is made for the return of samples they shall be disposed of as provided in § 281.22 for unused standard samples.

(b) Surplus samples representing tea which has been finally rejected should be destroyed, or, after being denatured, should be sold for manufacturing purposes under the Tea Importation Act (35 Stat. 163; 21 U. S. C. 41).

§ 281.19 *Tea standards.* (a) Samples for standards of the following teas, prepared, identified, and submitted by the Board of Tea Experts on February 16, 1955, are hereby fixed and established as the standards of purity, quality, and fitness for consumption under the Tea Importation Act for the year beginning May 1, 1955, and ending April 30, 1956:

(1) Formosa Oolong.
(2) Black (for all black teas except as listed below).
(3) Formosa Black (Formosa Black and Congou type).
(4) Japan Black.
(5) Japan Green.
(6) Scented Canton type.
(7) Canton Oolong type.

These standards apply to tea shipped from abroad on or after May 1, 1955. Tea shipped prior to May 1, 1955, will be governed by the standards which became effective May 1, 1954 (19 F. R. 1141).

(b) The Board of Tea Experts shall prepare duplicate samples of the standards for teas.

(Sec. 2, 29 Stat. 605, as amended; 21 U. S. C. 42)

§ 281.20 *Effective date of tea standards.* The standards prepared and submitted to the Secretary of Health, Education, and Welfare by the Board of Tea Experts, appointed by him on or before February 15 of each year, shall be fixed and established as standards under the act and shall be in effect from the 1st day of May of each year until April 30, inclusive, of the following year, except that tea shipped from abroad prior to May 1 of any year shall be governed by the standards in effect at the time of shipment. Such standards for each year will be published in the FEDERAL REGISTER.

§ 281.21 *To whom standards will be furnished.* (a) A quantity of tea of the approved standards will be repacked in half-pound tin containers by competent tea packers under the constant supervision of an officer of the Food and Drug Administration and full sets will be furnished the Board of Tea Appeals, the supervising tea examiner, and the examiners of tea at all the tea examining stations.

(b) Standards will be furnished to actual importers and regular tea brokers on application to the supervising tea examiner, at the actual cost of the same.

§ 281.22 *Disposition of obsolete standards.* After standard samples have served their purpose and new season samples have been submitted, the old samples may be included in quarterly sales of unclaimed goods, and the proceeds paid into the Treasury, after deducting expenses of advertisement and sale, the designation on the packages showing such teas to have been used as Government standards to be obliterated before delivery to purchaser.

§ 281.23 *Instructions to examiners.* (a) Examiners are instructed not to pass upon samples representing importations of tea imported separately from the importation; neither shall they give nonofficial opinions concerning samples.

(b) The examination of tea in comparison with the standards under this act shall be made according to the usages and customs of the tea trade, including the testing of an infusion in boiling water and, if necessary, chemical analysis; and examiners are advised, inasmuch as they must not under the law admit any tea inferior to the standards in purity, quality, and fitness for consumption, to employ the present methods of determining the presence of artificial coloring and other impurities. (See § 281.31.)

§ 281.24 *Testing of teas.* (a) In comparing with standards, examiners are to test all the teas for quality, for impurity consisting of artificial coloring or facing matter, and other impurity, and for quality of infused leaf. Quality shall be ascertained by drawing, according to the custom of the tea trade, with the weight of a silver half dime to the cup. The quality must be equal to standard, but the flavor may be that of a different district, as long as it is equally fit for consumption. As an illustration, a Teenkai may be equal to a Moyune, but a distinctly smoky or rank Fychow or Wenchow of sour character is not considered equal to the first two mentioned.

(b) Tea dust, fannings, siftings, and offgrades, including broken tea (BT), broken mix (BM), and Bohea when so marked and for which there is no specific standard, should be tested for quality, purity, and fitness for consumption in comparison with their respective leaf standards.

§ 281.25 *Testing quality of infused leaf.* In order to test the quality of the infused leaf in comparison with the standard, a second drawing should be made of double weight. Before pouring off the water, examine for an excess of "floaters" (woody stems which remain floating after the leaf is thoroughly infused) to determine whether they are in sufficient quantity to reduce the quality of the infusion below that of the standard. After pouring off the water the infused leaf should be taken out so as to exhibit the lower side which rested against the cup. Should the mass show a larger quantity of exhausted or decayed leaf than the standard it affords sufficient evidence to be judged inferior in quality and consequently to be rejected.

§ 281.26 *Macao or Canton congou and brick tea standards.* Macao or Canton congou and brick tea should be compared with the standard for China congou. The mustiness or damaged flavor exhibited in certain Canton teas would be just cause for rejection.

§ 281.27 *Teas imitating China green teas.* Whenever Japans, Ceylons, Indias, or any other teas are made up to imitate the green teas of China, they are to be examined in comparison with the China green standards.

§ 281.28 *Powchong Formosa oolong teas.* All Powchong (scented) Formosa oolong teas should be examined in comparison with the Formosa standard.

§ 281.29 *Tea dust.* Tea dust or broken leaf mixed with other teas or separate, made to imitate gunpowder or other teas, with the use of paste or gum, or any other substance, would justly be rejected.

§ 281.30 *Test for paraffin and similar substances.* If the examiner suspects the presence of paraffin or any similar substance, he should make the following test in comparison with the standard: Spread the tea between two sheets of unglazed white paper. Place thereon a hot iron. The greasy substance, if any, will appear on the paper, and if not equal to the standard the tea would justly be rejected.

§ 281.31 *Tests for impurities.* (a) To examine for impurities the following tests may be used in comparison with the standard:

(1) Read test, with additions and modifications, and the cup test, double-weight.—Place 2 ounces of tea in a sieve 5 or 6 inches in diameter, having 60 meshes to the inch and provided with a top. Sift a small quantity of the dust onto a semiglazed white paper about 8 by 10 inches. The amount of dust placed on the paper should be approximately 1 grain. To get the requisite amount of dust it is sometimes necessary to rub the leaf gently against the bottom of the sieve, but this must not be done until the sieve has been well shaken over the test paper. Pour the dust thus collected from the paper into the scales, weigh out 1 grain, and return this quantity to the same paper, distributing it well over the surface of the paper. Then place the paper on a plain, firm surface, preferably glass or marble, and crush the dust by pushing over it, with considerable pressure, a flat steel spatula about 5 inches long. Do this repeatedly until the tea dust is ground almost to a powder and the particles of coloring matter or other impurities, if any, are spread or streaked on the paper, so as to become more apparent. Brush off the loose dust and examine the paper by means of a simple lens magnifying 7½ diameters. In distinguishing these particles and streaks bright light is essential.

(2) The crushed leaf in either black or green tea appears in such quantity that there is no chance of mistaking the

leaf for artificial coloring, facing material, or other impurities.

(3) The test is performed in comparison with the standard, and, if the tea is clearly equal to the standard with respect to artificial coloring, facing matter, or other impurities, the operation need not be repeated. If particles of artificial coloring, facing, or other impurities are found in the sample under comparison with the standard repeat this operation a sufficient number of times to be sure whether or not the tea contains impurities in excess of the standard.

(4) Repeat the operation, using semi-glazed black paper instead of the white paper. This black-paper test shows the presence of facing and other impurities, such as talc, gypsum, barium sulfate, clay, and kaolin.

(5) If the tea under examination is found, by the foregoing tests, to contain more impurities than the standard, draw samples from packages representing at least 5 percent of the line in question, and subject each sample to the tests to ascertain whether or not the majority contain impurities in excess of the standard.

(6) The foregoing tests may be applied to tea of all varieties.

(b) Should the examination of the sample by the cup test, double-weight, for scum, sediment, etc., or the Read test, or both, disclose the presence of more impurities than the standard, a pound sample should be sent to the nearest district of the Food and Drug Administration and an analysis made in comparison with the standard to determine whether it contains more impurities than the standard. If the tea in question is found to contain more impurities than the standard, it would properly be rejected as not being equal to the standard in purity.

(c) All extraneous substances are impurities, and the presence of any may be detected in any way found efficient.

§ 281.34 *Tolerance for fine tea particles.* Except for teas listed under § 281.24 (b), the amount by weight of fine tea parties that will pass through a wire sieve having 30 openings per linear inch in either direction and made of wire with a diameter of 0.01 inch, must not exceed 4 percent. Before condemning any tea for fine particles in excess of 4 percent, examiners shall sieve at least 4 representative samples, each taken from a different package in a shipment containing four or more packages, or where a lesser number of packages is involved, examiners shall sieve a representative sample from each package.

§ 281.35 *Tea inferior to the standard in any requisite is justly rejected.* Should a tea prove on examination to be inferior to the standard in any one of the requisites—namely, quality, quality of infused leaf, or purity—it would justly be rejected, notwithstanding the fact that it may be superior to the standards in some of the qualifications. No consideration shall be given to the appearance or so-called style of the dry leaf.

§ 281.36 *Action based on result of examination.* (a) If, after examination, the tea is found not to be prohibited under the act, a release permit shall at once be granted to the importer, declaring that the tea is not within the prohibition of the Tea Importation Act; but if, on examination, such tea, or merchandise described as tea, is found in the opinion of the examiner, to come within the prohibitions of the law and of the regulations in this part, the importer shall be immediately notified (T. I. S. Cat. No. 6), and the tea, or merchandise described as tea, so returned, shall not be released by the customhouse authorities, unless on a reexamination called for by the importer the return of the examiner shall be found erroneous. Should a portion only of the invoice be passed by the examiner as correct, a permit of delivery shall be granted for that portion and the remainder held as provided in section 6 of the act (29 Stat. 606; 21 U. S. C. 47).

(b) In all cases of rejections by examiners, the importers should be notified of the reason for rejection; that is, whether it be on the ground of quality, character of infused leaf, dust, or admixture with foreign substance.

§ 281.37 *Procedure for protest against findings.* In case the collector of customs, importer, or consignee shall protest against the finding of the examiner, the matter in dispute shall be referred for decision to the United States Board of Tea Appeals, designated by the Secretary of Health, Education, and Welfare, and if such board shall, after due examination, find the tea in question to be equal in purity, quality, and fitness for consumption, as compared with the proper standards, a permit shall be issued by the collector of customs for its release and delivery to the importer; but if, upon such final re-examination by such board, the tea shall be found to be inferior in purity, quality, and fitness for consumption, as compared with the said standards, the importer or consignee shall give a bond, unless he has previously done so, with security satisfactory to the collector, to export said tea out of the limits of the United States within a period of 6 months after such final re-examination; and if the same shall not have been exported within the time specified, the collector of customs, at the expiration of that time, shall cause the same to be destroyed.

§ 281.38 *Procedure by importer for review.* (a) If the importer desires teas rejected by the examiner to be reviewed by the United States Board of Tea Appeals, as provided in section 6 of the said act, he shall, within 30 days after he has been notified of such return, file a written application with the collector in the form T. I. S. Cat. No. 20. The collector will thereupon forward such application to the United States Board of Tea Appeals, designated by the Secretary of Health, Education, and Welfare for review of the matter in dispute, and the proceedings shall be according to section 8 of the act.

(b) The re-examination of the tea samples must be restricted to the samples put up and sealed by the examiner at ports where qualified tea examiners are stationed, or by the chief officer of the customs, if there is no qualified tea examiner so stationed, in the presence of the importer or consignee, if he so desires. In either case the samples should be transmitted to the United States Board of Tea Appeals by the tea examiner, together with a copy of the finding of the examiner, setting forth the cause of condemnation.

(c) These samples for re-examination should weigh at least 1 pound, and should be put up in tins securely labeled (T. I. S. Cat. No. 21) and well wiped and seasoned. Half of such samples shall be utilized for the examination by the Board of Tea Apppeals and for return to the port of entry with the decision, as heretofore, and the remaining half pound, if the tea be rejected by said board, shall be distributed among the various examiners for their information and guidance.

(d) Teas rejected by tea examiners and rejections affirmed by the United States Board of Tea Appeals cannot be re-examined.

§ 281.39 *Rejected tea.* Rejected tea can only be released or withdrawn for exportation, for transportation and exportation, or for manufacturing purposes under the Tea Importation Act (35 Stat. 163; 21 U. S. C. 41), as the case may be.

§ 281.40 *Exportation of rejected teas.* (a) Teas to be exported for the reason that they are within the prohibition of the statute will be entered for exportation on Customs Form No. 7515, and bond on Customs Form No. 7557 shall be given for their exportation in a penal sum equal to double the value of the tea, provided consumption entry bond (Form No. 7551 or Form No. 7553) was not previously given.

(b) Whenever a bond is given to export any condemned tea in pursuance of the act, it will be canceled upon the filing of an outward bill of lading and a duly authenticated certificate of clearance from the customs officer supervising the lading thereof, as in the case of rejected foods and drugs (T. D. 28341), and all accrued charges must be paid before issuance of permit for exportation.

(c) At interior ports the export entry shall be made for transportation and immediate exportation in bond.

§ 281.41 *Reimportation of exported teas forbidden.* (a) No imported teas which have been rejected by an examiner, or by the United States Board of Tea Appeals, and exported under the provisions of this act, shall be reimported into the United States under the penalty of forfeiture for a violation of this prohibition.

(b) Customs officers will make seizure of any tea so imported.

§ 281.42 *Destruction of condemned tea.* Whenever condemned tea is to be destroyed it must be conveyed to some suitable place, and proper means, to be prescribed by the examiner, must be used for its effectual destruction, which shall be effected in the presence of an officer of customs, detailed by the collector for the purpose. Before the tea is destroyed a particular description or statement of the same must be prepared containing the name of the importer or owner, the date of importation, the name of the vessel, and the place from which imported, with the character and quantity of the tea and the invoice value. The fact of its destruction must be certified on said statement by the officer detailed as aforesaid, which statement must be filed in the customhouse.

§ 281.43 *Duties of supervising tea examiner.* (a) The supervising tea examiner is charged with the immediate supervision of all matters relating to the enforcement of the Tea Importation Act, and particularly the securing of uniformity in the treatment of imported teas at all the points of examination. He is also to perform such duties in connection with tea under the Food, Drug, and Cosmetic Act as may be assigned to him.

(b) For the purpose of securing uniformity in the treatment of teas each tea examiner will send to the supervising tea examiner one-half pound samples of the teas rejected by him, also such other samples of teas as the supervising tea examiner may direct. To each sample a label (T. I. S. Cat. No. 2) shall be affixed.

(c) The examiner of tea at each port where a qualified tea examiner is stationed shall prepare and forward to the supervising tea examiner and to the chairman of the United States Board of Tea Appeals, as soon as practicable after the close of each month, a report (T. I. S. Cat. No. 3), showing details as to every shipment of tea examined by the tea examiner. This information the tea examiner should compile from his report of "Teas Imported and Examined" (T. I. S. Cat. No. 4) which should always be kept up to date.

PART 285—REGULATIONS UNDER THE FEDERAL CAUSTIC POISON ACT

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AUTHORITY: §§ 285.1 to 285.32 issued under sec. 9 (c) (1), 44 Stat. 1409; 15 U. S. C. 409 (c) (1).

CROSS REFERENCES: For regulations relating to enforcement of customs laws, see 19 CFR Part 23. For regulations relating to invoices, entry, and assessment of duties, see 19 CFR Part 8. For regulations regarding the examination, classification, and disposition of foods, drugs, devices, cosmetics, insecticides, fungicides, and caustic or corrosive substances, see 19 CFR 12.1–12.6. For regulations relating to consular invoices, and documentation of merchandise, see 22 CFR Part 114.

§ 285.1 *Definitions.* (a) The word "container" as used in the regulations in this part means a retail parcel, package, or container suitable for household use and employed exclusively to hold any dangerous caustic or corrosive substance defined in the act.

(b) The words "suitable for household use" mean and imply adaptability for ready or convenient handling in places where people dwell.

§ 285.2 *Scope of the act.* The provisions of the act apply to any container which has been shipped or delivered for shipment in interstate or foreign commerce, as defined in section 2 (c) of the act (44 Stat. 1407; 15 U. S. C. 402), or which has been received from shipment in such commerce for sale or exchange, or which is sold or offered for sale or held for sale or exchange in any Territory or possession or in the District of Columbia.

LABELS

§ 285.3 *Placement.* The label or sticker shall be so firmly attached to the container that it will remain thereon while the container is being used, and be so placed as readily to attract attention.

§ 285.4 *Required wording.* (a) The common name of the dangerous caustic or corrosive substance which shall appear on the label or sticker is the name given in section 2 (a) of the act (44 Stat. 1406; 15 U. S. C. 402) or any other name commonly employed to designate and identify such substance.

(b) Preparations within the scope of the act bearing trade or fanciful names shall, in addition, be labeled with the common name of the dangerous caustic or corrosive substance contained therein and comply with all the other requirements of the act and of the regulations in this part.

§ 285.5 *Manufacturer; distributor.* If the name on the label or sticker is other than that of the manufacturer, it shall be qualified by such words as "packed for," "packed by," "sold by," or "distributed by," as the case may be, or by other appropriate expression.

§ 285.6 ***Uncondensed Gothic capital letters to be used for labeling "Poison."*** The following are styles of uncondensed Gothic capital letters 24-point (type face) size:

POISON

POISON

When letters of not less than 24-point size are required on a label in stating the word "poison" they must not be smaller than those above set forth.

§ 285.7 *Directions for treatment.* Except as provided in § 285.8, the container shall bear in all cases upon the label or sticker thereof, immediately following the word "Poison," directions for treatment in the case of internal personal injury; in addition, if the substance may cause external injury, directions for appropriate treatment shall be given. The directions shall prescribe such treatments for personal injury as are sanctioned by competent medical authority, and the materials called for by such directions shall be, whenever practicable, such as are usually available in the household.

§ 285.8 *Directions for treatment; exemption.* Manufacturers and wholesalers only, at the time of shipment or delivery for shipment, are exempted from placing directions for treatment on the label or sticker of any container for other than household use, but in any event the information required by section 2 (b) (1), (2), and (3) of the act (44 Stat. 1407; 15 U. S. C. 402) and the regulations in this part shall be given.

§ 285.9 *Directions for treatment must be placed on container by person offering such container for general sale or exchange.* A person who receives from a manufacturer or wholesaler any container which under the conditions set forth in section 2 (b) (4) of the act and § 285.8 does not bear at the time of shipment directions for treatment in the case of personal injury must place such directions on the label or sticker if he offers such container for general sale or exchange.

GUARANTY

§ 285.10 *Specific guaranty.* If a guaranty in respect to any specific lot of dangerous caustic or corrosive substances be given, it shall be incorporated in or attached to the bill of sale, invoice, or other schedule bearing the date and the name and quantity of the substance sold, and shall not appear on the label or package. The following are forms of specific guaranties:

(a) Substances for both household use and other than household use:

> The undersigned guarantees that the retail parcels, packages, or containers of the dangerous caustic or corrosive substance or substances listed herein (or specifying the substances) are not misbranded within the meaning of the Federal Caustic Poison Act.
>
> (Signature and address of guarantor)

(b) Substances for other than household use (this form may be issued only by a manufacturer or wholesaler (§§ 285.8, 285.9)):

> The dangerous caustic or corrosive substance or substances listed herein (or specifying the substances) in retail parcels, packages, or containers suitable for household use are for other than household use and are guaranteed not to be misbranded within the meaning of the Federal Caustic Poison Act.
>
> (Name and address of manufacturer or wholesaler)

§ 285.11 *General guaranty.* In lieu of a particular guaranty for each lot of dangerous caustic or corrosive substances, a general continuing guaranty may be furnished by the guarantor to actual or prospective purchasers. The following are forms of continuing guaranties:

(a) Substances for both household use and other than household use:

> The undersigned guarantees that the retail parcels, packages, or containers of the dangerous caustic or corrosive substance or substances to be sold to -------------- are not misbranded within the meaning of the Federal Caustic Poison Act.
>
> (Date) (Signature and address of guarantor)

(b) Substances for other than household use (this form may be issued only by a manufacturer or wholesaler (§§ 285.8, 285.9)):

> The dangerous caustic or corrosive substance or substances in retail parcels, packages, or containers suitable for household use to be sold to ----------------- are for other than household use, and guaranteed not to be misbranded within the meaning of the Federal Caustic Poison Act.
>
> (Date) (Signature and address of manufacturer or wholesaler)

SAMPLES

§ 285.12 *Collection of samples.* Samples for examination by or under the direction and supervision of the Food and Drug Administration shall be collected by:

(a) An authorized agent in the employ of the Department of Health, Education, and Welfare;

(b) Any officer of any State, Territory, or possession, or of the District of Columbia, authorized by the Secretary of Health, Education, and Welfare.

§ 285.13 *Where samples may be collected.* Caustic or corrosive substances within the scope of this act (44 Stat. 1406; 15 U. S. C. 401–411) may be sampled wherever found.

§ 285.14 *Analyzing of samples.* Samples collected by an authorized agent shall be analyzed at the laboratory designated by the Food and Drug Administration. Only such samples as are collected in accordance with §§ 285.12, 285.13 may be analyzed by or under the direction and supervision of the Food and Drug Administration. Upon request one subdivision of the sample, if available, shall be delivered to the party or parties interested.

MISCELLANEOUS

§ 285.15 *Investigations.* Authorized agents in the employ of the Department of Health, Education, and Welfare may make investigations, including the inspection of premises where dangerous caustic and corrosive substances subject to the act are manufactured, packed, stored, or held for sale or distribution, and make examinations of freight and other transportation records.

§ 285.16 *Analysis.* (a) The methods of examination or analysis employed shall be those prescribed by the Association of Official Agricultural Chemists, when applicable, provided, however, that any method of analysis or examination satisfactory to the Food and Drug Administration may be employed.

(b) All percentages stated in the definitions in section 2 (a) of the Caustic Poison Act shall be determined by weight.

§ 285.17 *Hearings.* Whenever it appears from the inspection, analysis, or test of any container that the provisions of section 3 or 6 of the Caustic Poison Act (44 Stat. 1407, 1409; 15 U. S. C. 403, 406) have been violated and criminal proceedings are contemplated, notice shall be given to the party or parties against whom prosecution is under consideration and to other interested parties, and a date shall be fixed at which such party or parties may be heard. The hearing shall be held at the office of the Food and Drug Administration designated in the notice and shall be private and confined to questions of fact. The parties notified may present evidence, either oral or written, in person or by attorney, to show cause why the matter should not be referred for prosecution as a violation of the Federal Caustic Poison Act.

§ 285.18 *Hearings; when not provided for.* No hearing is provided for when the health, medical, or drug officer or agent of any State, Territory, or possession, or of the District of Columbia, acts under the authority contained in section 8 of the Federal Caustic Poison Act (44 Stat. 1409; 15 U. S. C. 408) in reporting a violation direct to the United States attorney.

§ 285.19 *Publication.* (a) After judgment of the court in any proceeding under the Federal Caustic Poison Act, notice shall be given by publication. Such notice shall include the findings of the court and may include the findings of the analyst and such explanatory statements of fact as the Secretary of Health, Education, and Welfare may deem appropriate.

(b) This publication may be made in the form of a circular, notice, or bulletin, as the Secretary of Health, Education, and Welfare may direct.

(c) If an appeal be taken from the judgment of the court before such publication, that fact shall appear.

IMPORTS

§ 285.20 *Required label information.* Containers which are offered for import shall in all cases bear labels or stickers having thereon the information required by section 2 (b) (1), (2), and (3) of the Federal Caustic Poison Act and the directions for treatment in the case of personal injury, except such directions need not appear on the label or sticker at the time of shipment by a wholesaler or manufacturer for other than household use.

§ 285.21 *Enforcement of provisions.* The enforcement of the provisions of the Federal Caustic Poison Act as they relate to imported dangerous caustic or corrosive substances, will, as a general rule, be under the direction of the chief of the local inspection district of the Food and Drug Administration, Department of Health, Education, and Welfare, and collectors of customs acting as administrative officers in carrying out directions relative to the detention, exportation, and sale, or other disposition of such substances and action under the bond in case of noncompliance with the provisions of the Federal Caustic Poison Act.

§ 285.22 *Delivery of containers.* Containers shall not be delivered to the consignee prior to report of examination, unless a bond has been given on the appropriate form for the amount of the full invoice value of such containers, together with the duty thereon, and on refusal of the consignee to return such containers for any cause to the custody of the collector when demanded, for the purpose of excluding them from the country or for any other purpose, the consignee shall pay an amount equal to the sum named in the bond, and such part of the duty, if any, as may be payable, as liquidated damages for failure to return to the collector on demand all containers covered by the bond.

§ 285.23 *Invoices.* As soon as the importer makes entry, the invoices covering containers and the public stores packages shall be made available, with the least possible delay, for inspection by the representative of the district. When no sample is desired the invoice shall be stamped by the district "No sample desired, Food and Drug Administration, Department of Health, Education, and Welfare, per (initials of inspecting officer)."

§ 285.24 *Samples.* On the same day that samples are requested by the district, the collector or appraiser shall notify the importer that samples will be taken, that the containers must be held intact pending a notice of the result of inspection and analysis, and that in case the containers do not comply with the requirements of the Federal Caustic Poison Act, they must be returned to the collector for disposition. This notification may be given by the collector or appraiser through individual notices to the importer or by suitable bulletin notices posted daily in the customhouse.

§ 285.25 *No violation; release.* As soon as examination of the samples is completed, if no violation of the act is detected, the chief of the district shall send a notice of release to the importer and a copy of this notice to the collector of customs for his information.

§ 285.26 *Violation.* (a) If a violation of the Federal Caustic Poison Act is disclosed, the chief of the district shall send to the importer due notice of the nature of the violation and of the time and place where evidence may be presented, showing that the containers should not be refused admission. At the same time similar notice regarding detention of the containers shall be sent to the collector, requesting him to refuse delivery thereof or to require their return to customs custody if by any chance the containers were released without the bond referred to in § 285.22. The time allowed the importer for representations regarding the shipment may be extended at his request for a reasonable period to permit him to secure such evidence.

(b) If the importer does not reply to the notice of hearing in person or by letter within the time allowed on the notice, a second notice, marked "second and last notice," shall be sent at once by the chief of the district, advising him that failure to reply will cause definite recommendation to the collector that the containers be refused admission and that the containers be exported within 3 months under customs supervision.

§ 285.27 *Rejected containers.* (a) In all cases where the containers are to be refused admission, the chief of the district within 1 day after hearing, or, if the importer does not appear or reply within 3 days after second notice, shall notify the collector in duplicate accordingly.

(b) Not later than 1 day after receipt of this notice the collector shall sign and transmit to the importer one of the copies, which shall serve as notification to the importer that the containers must be exported under customs supervision within 3 months from such date, as provided by law; the other notice shall be retained as office record and later returned as a report to the chief of the district. In all cases the importer shall return his notice to the collector, properly certified as to the information required, as the form provides.

§ 285.28 *Relabeling of containers.* (a) If containers are to be released after relabeling, a notice shall be sent by the chief of district direct to the importer, a carbon copy being sent to the collector. This notice must state specifically the conditions to be performed, so as to bring the performance thereof under the provisions of the customs bonds on consumption and warehouse entries, these bonds including provisions requiring compliance with all of the requirements of the Federal Caustic Poison Act and all regulations and instructions issued thereunder. The notice will also state the officer to be notified by the importer when the containers are ready for inspection.

(b) The importer must return the notice to the collector or chief of district, as designated, with the certificate thereon filled out, stating that he has complied with the prescribed conditions and that the containers are ready for inspection at the place named.

(c) This notice will be delivered to the inspection officer, who, after inspection, will endorse the result thereof on the back of the notice and return the same to the collector or to the chief of district, as the case may be.

(d) When the conditions to be complied with are under the supervision of the chief of district, and these conditions have been fully met, he shall release the containers to the importer, sending a copy of the notice of release to the collector for his information. If the containers have not been properly relabeled within the period allowed, the chief of district shall immediately give notice in duplicate to the collector of the results of inspection. The collector shall sign and immediately transmit one copy of the notice to the importer and proceed in the usual manner.

(e) If the containers are detained, subject to relabeling to be performed under the collector's supervision, the collector, as soon as relabeling is accomplished, will notify the importer that the containers are released.

(f) If the containers have not been properly relabeled within the period allowed, their sale after labeling as required by the act or other disposition must be effected by the collector.

(g) When the final action has been taken on containers which have been refused admission, sold, or otherwise disposed of as provided for by the act or which have been relabeled under the collector's supervision, the collector shall send to the chief of district a notice of such final action, giving the date and disposition.

(h) When relabeling is allowed the importer must furnish satisfactory evidence as to the identity of the containers before release is given. The relabeling must be done at a stated place and apart from other containers of a similar nature.

(i) When containers are shipped to another port for relabeling or exportation, they must be shipped under customs carrier's manifest, in the same manner as shipments in bond.

(j) Collectors of customs will perform the inspection service whenever containers are to be exported, sold, or otherwise disposed of, and in other cases when there is no officer of the district available.

(k) Collectors of customs and representatives of the district will confer and arrange the apportionment of the inspection service according to local conditions. Officers of the district will, whenever feasible, perform the inspection service in connection with relabeling.

§ 285.29 *Penalties.* (a) In case of failure to comply with the instructions or recommendations of the chief of district as to conditions under which containers may be disposed of, the collector shall notify the chief of district in all cases coming to his attention within 3 days after inspection or after the expiration of the 3 months allowed by law if no action is taken.

(b) The chief of district, upon receipt of the above-described notice, and in all cases of failure to meet the conditions imposed in order to comply with the provisions of the Federal Caustic Poison Act coming directly under his supervision, shall transmit to the collector of customs such evidence as he may have at hand tending to indicate the importer's liability and make a recommendation accordingly.

(c) The collector, within 3 days of the receipt of this recommendation, whether favorable or otherwise, shall notify the importer that, the legal period of 3 months for exportation or relabeling having expired, action will be taken within 30 days to enforce the terms of the bond.

§ 285.30 *Nonlaboratory ports.* (a) At the ports of entry where there is no district of the Food and Drug Administration, the collector or deputy, on the day when the first notice of expected shipment of containers is received, either by invoice or entry, shall notify the chief of district in whose territory the port is located.

(b) On the day of receipt of such notice the chief of district shall mail to the collector appropriate notice, if no sample is desired. This notice serves as an equivalent to stamping the invoices at district ports with the legend "No sample desired, Food and Drug Administration, Department of Health, Education, and Welfare, per (initials of inspecting officer)."

(c) If samples are desired, the chief of district shall immediately notify the collector.

(d) The collector at once shall forward samples, accompanied by description of shipment.

(e) When samples are desired from each shipment of containers, the chief of district shall furnish to collector and deputies at ports within the district's territory a list of such containers, indicating the size of sample necessary. Samples should then be sent promptly on arrival of containers without awaiting special request.

(f) In all other particulars the procedure shall be the same at nonlaboratory ports as at laboratory ports, except that the time consumed in delivery of notices by mail shall be allowed for.

§ 285.31 *Chief of district as customs officer.* The chief of district shall be deemed a customs officer in enforcing import regulations.

§ 285.32 *Enforcement agency.* The Federal Caustic Poison Act shall be enforced by the Food and Drug Administration, Department of Health, Education, and Welfare.

PART 290—REGULATIONS FOR THE ENFORCEMENT OF THE FEDERAL IMPORT MILK ACT

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AUTHORITY: §§ 290.1 to 290.52 issued under sec. 3, 44 Stat. 1102; 21 U. S. C. 143. Interpret or apply sec. 2, 44 Stat. 1101; 21 U. S. C. 142.

CROSS REFERENCES: For Agricultural Research Service regulations concerning tubercular cattle, see 9 CFR Parts 51 and 77. For Agricultural Research Service regulations, see 9 CFR Chapter III. For customs regulations concerning importation of milk and cream, see 19 CFR 12.7. For regulations of the Agricultural Marketing Service (Marketing Agreements and Orders) covering marketing areas for milk, see 7 CFR Chapter IX.

§290.1 *Short title of the act.* For the purposes of the regulations in this part the act (44 Stat. 1101; 21 U. S. C. 141–149) "To regulate the importation of milk and cream into the United States for the purpose of promoting the dairy industry of the United States and protecting the public health" shall be known and referred to as "the Federal Import Milk Act."

§ 290.2 *Scope of the act.* The provisions of the act apply to all milk and cream offered for import into the continental United States.

DEFINITIONS

§ 290.3 *Milk.* For the purposes of the act and of the regulations in this part:

Milk is the whole, fresh, clean, lacteal secretion obtained by the complete milking of one or more healthy cows, properly fed and kept, excluding that obtained within 15 days before and 5 days after calving, or such longer period as may be necessary to render the milk practically colostrum free.

§ 290.4 *Cream.* Cream is that portion of the milk, rich in milk fat, which rises to the surface of milk on standing or is separated from it by centrifugal force. (See §§ 18.500 to 18.515 of this chapter).

§ 290.5 *Condensed milk.* Condensed milk, as the term is used in section 3, paragraph 2, of the Import Milk Act, includes evaporated milk in the manufacture of which sterilization of the milk and cream is a necessary and usual process; it includes sweetened condensed milk only if it is prepared by a process which insures sterilization of the milk and cream. Condensed milk, as the term is used in section 3, paragraph 3, of the Import Milk Act, means sweetened condensed milk.

§ 290.6 *Evaporated milk.* Evaporated milk conforms to the definition and standard of identity for such food as set out in § 18.520 of this chapter.

§ 290.7 *Sweetened condensed milk.* Sweetened condensed milk conforms to the definition and standard of identity for such food as set out in § 18.530 of this chapter.

§ 290.8 *Pasteurization.* Pasteurization is the process of heating every particle of milk or cream to at least 143° F., and holding it at such temperature continuously for at least 30 minutes, or to at least 161° F., and holding it at such temperature continuously for at least 15 seconds.

§ 290.9 *Shipper.* A shipper is anyone, other than a common carrier, who ships, transports, or causes to be shipped or transported into the United States milk or cream owned by him.

§ 290.10 *Secretary.* Secretary means the Secretary of Health, Education, and Welfare.

§ 290.11 *Commissioner.* Commissioner means the Commissioner of Food and Drugs.

§ 290.12 *Physical examination of cows.* (a) Physical examination of any and all cows in herds producing milk or cream which is to be shipped or transported into the United States shall be made by an authorized veterinarian of the United States or of any State or municipality thereof or of the country in which such milk or cream is produced to determine whether such cow or cows are in a healthy condition. Such examination shall be made as often as the Secretary may deem necessary and, in any event, shall have been made within one year previous to the time of the importation.

(b) The result of the physical examination shall be set forth in the form prescribed by the Secretary.

§ 290.13 *Tuberculin test.* (a) Except as provided in § 290.24, any and all animals in herds producing milk or cream which is to be shipped or transported raw into the United States shall be free from tuberculosis, as determined by a tuberculin test applied by an official veterinarian of the United States or of any State or municipality thereof or of the country in which such milk or cream is produced. Such test shall be made as often as the Secretary may deem necessary and, in any event, shall have been made within 1 year previous to the time of the importation. All animals showing positive or suspicious reactions to the tuberculin test must be permanently removed from the herd.

(b) The results of the tuberculin test and all facts concerning the disposal of reacting or suspected animals shall be set forth in the form prescribed by the Secretary.

§ 290.14 *Sanitary inspection of dairy farms.* The sanitary conditions of any dairy farm producing milk or cream to be shipped or transported into the United States or to a plant from which milk or cream is to be shipped or transported into the United States must score at least 50 points out of 100 points, according to the methods for scoring as provided by the score card for sanitary inspection of dairy farms used by the Dairy Husbandry Branch, Agricultural Research Service of the United States Department of Agriculture at the time of scoring.

§ 290.15 *Sanitary inspection of plants.* The sanitary conditions of any plant handling milk or cream any part of which is to be shipped or transported into the United States shall score at least 50 points out of 100 points according to the methods for scoring as provided by the score card for sanitary inspection of such plants used by the Dairy Husbandry Branch, Agricultural Research Service of the United States Department of Agriculture at the time of scoring.

§ 290.16 *Scoring.* Scoring of sanitary conditions required by §§ 290.14, 290.15 shall be done by an official inspector of the United States or of any State or municipality thereof or of the country in which the dairy farm or plant is located.

§ 290.17 *Pasteurization; equipment and methods.* All dairy farms and plants at which any milk or cream is pasteurized for shipment or transportation into the United States shall employ adequate pasteurizing machinery of a type easily cleaned and of sanitary construction capable of holding every portion of the milk or cream at the required temperature for the required time. Such pasteurizing machinery shall be properly equipped with accurate time and temperature recording devices, which shall be kept at all times in good working order. The temperature at the time of heating and holding must invariably be recorded on thermograph charts, initialed, numbered, and dated by the official having jurisdiction over such farms and plants. All thermograph charts shall be held for a period of 1 year unless within that period they have been examined and released by such authorized agents as are designated by the Secretary.

§ 290.18 *Method of bacterial count.* The bacterial count of milk and cream refers to the number of viable bacteria as determined by the standard plate method of the American Public Health Association in use at the time of the examination.

§ 290.19 *Authority to sample and inspect.* Inspectors engaged in the enforcement of the Import Milk Act are empowered to test for temperature, to take samples of milk or cream, and to use such means as may be necessary for these purposes.

§ 290.20 *Permits for pasteurized milk or cream.* Permits to ship or transport pasteurized milk or cream into the United States will be granted only upon compliance with the requirements of clauses 1 and 3 of section 2 of the Import Milk Act, §§ 290.12, 290.14, 290.15, as applicable.

§ 290.21 *Permits for raw milk or cream.* Except as provided in § 185.24, permits to ship or transport raw milk or cream into the United States will be granted only when the milk or cream comes from dairy farms or plants where pasteurization is not carried on and then only upon compliance with the requirements of clauses 1, 2, and 3 of section 2 of the Import Milk Act, §§ 290.12 to 290.15, as applicable.

§ 290.22 *Permits granted on certificates.* In the discretion of the Secretary, a permit may be granted on a duly certified statement signed by a duly accredited official of an authoried department of any foreign government or of any State of the United States or any municipality thereof. Such statement shall be in the form of a certificate prescribed by the Secretary, and shall have attached thereto, as a part thereof, signed copies of reports prescribed by §§ 290.12, 290.13, and also by §§ 290.14, 290.15, as applicable. The necessary inspections and examinations upon which the reports are based shall be made by persons who are acting under the direct supervision of the certifying official.

§ 290.23 *Permits waiving clause 4, section 2 of the Import Milk Act.* The Secretary, in his discretion, will issue to a shipper who is an operator of a condensery a permit waiving the requirements of clause 4, of section 2 of the Import Milk Act and allowing milk and cream containing not to exceed 1,200,000 bacteria per cubic centimeter to be shipped or transported into the United States if the condensery is located within a radius of 15 miles of the point of production of the milk and cream and such milk and cream are to be sterilized in the manufacture of condensed milk.

§ 290.24 *Permits waiving clauses 2 and 5, section 2 of the Import Milk Act.* A permit to ship or transport raw milk into the United States will contain a waiver of clauses 2 and 5 of section 2 of the Import Milk Act when the shipper is an operator of a creamery or condensery, or is a producer shipping or transporting to a creamery or condensery and the creamery or condensery is located in the United States within a radius of 20 miles of the point of production of such milk, and the milk, prior to its sale, use, or disposal, is pasteurized, condensed, or evaporated.

§ 290.25 *Temporary permits.* A temporary permit will be granted only upon a satisfactory showing that the applicant therefor has been unable to obtain the necessary inspections required by the applicable provisions of section 2 of the Import Milk Act. Temporary permits shall be valid until the Secretary shall provide for inspection to ascertain that clauses 1, 2, and 3 of section 2 of the Import Milk Act have been complied with.

§ 290.26 *Examination and inspection must be allowed.* Dairy farms and plants from which milk or cream is shipped or transported into the United States shall be open at all reasonable times to authorized agents for necessary examinations and inspections. Failure to permit such examinations and inspections may be considered cause for the suspension or revocation of the permit.

§ 290.27 *Application for permit.* Application for a permit to ship or transport milk or cream into the United States shall be made by the actual shipper upon forms prescribed by the Secretary. The request for forms of applications for permits should be addressed to Commissioner of Foods and Drugs, Food and Drug Administration, Department of Health, Education, and Welfare, Washington 25, D. C.

§ 290.28 *Permit number.* Each permit issued under the Import Milk Act, including each temporary permit, shall bear an individual number. The right to the use of such number is restricted solely to the permittee.

§ 290.29 *Form of tag.* Each container of milk or cream shipped or transported into the United States by such permittee shall have firmly attached thereto a tag in the following form, bearing the required information in clear and legible type:

Product____________________________
(State whether raw milk, pasteurized milk, raw cream, or pasteurized cream.)
Permit number______________________
Federal Import Milk Act.
Department of Health, Education, and Welfare.
Shipper____________________________
Address of shipper_________________

Provided, That in case of unit shipments consisting of milk only or cream only under one permit number, in lieu of each container being so marked, the vehicle of transportation, if sealed, may be tagged with the above tag, which should, in addition, show the number of containers and quantity of contents of each.

§ 290.30 *Suspension and revocation of permit.* A permit to ship or transport milk or cream into the United States may be suspended for cause at any time. A permit may be revoked for cause after opportunity to be heard has been accorded the permittee, who may appear in person, by attorney, or by letter and show cause why the permit should not be revoked.

§ 290.31 *Order to show cause why permit should not be revoked and temporary suspension of permit pending hearing.* When the Secretary has reason to believe that the holder of any permit for the shipment of milk or cream into the United States has failed to comply with the provisions of or has violated sections 141–149 of Title 21, United States Code, or any of the regulations in this part, or that the milk or cream shipped by the holder of the permit into the United States is not produced and handled in conformity with, or that the quality thereof does not conform to, all of the provisions of section 142 of Title 21, United States Code, the Secretary shall serve upon the permittee an order to show cause why such permit should not be revoked, and, pending the hearing upon such order, the Secretary may temporarily suspend such permit.

§ 290.32 *Docket or file number.* The order to show cause shall be assigned a docket or file number and the proceedings had thereunder shall thereafter be referred to by such number.

§ 290.33 *Service of order to show cause.* The order to show cause shall be addressed to the permittee, who shall be designated as the respondent, and shall be served upon the permittee by an employee of the Department of Health, Education, and Welfare or by registered mail, return receipt requested. If the respondent is a corporation, service shall be had upon the president, secretary, treasurer or statutory agent of the corporation.

§ 290.34 *Time and place of hearing.* The Secretary shall set a time and place for a hearing upon the order to show cause.

§ 290.35 *Designation of examiner.* The Secretary shall designate an employee of the Department of Health, Education, and Welfare as examiner to conduct the hearing, and such examiner may, in accordance with the rules of evidence applicable to administrative proceedings, admit or exclude any evidence presented and may limit the scope of any evidence admitted.

§ 290.36 *Appearance of respondent.* The respondent may appear in person or by counsel. All persons who appear at the hearing must conform to the standards of ethical conduct required of practitioners before the courts of the United States.

§ 290.37 *Testimony of witnesses.* The testimony of witnesses at the hearing shall be upon oath or affirmation administered by the examiner.

§ 290.38 *Admissibility of records.* Copies of the records of the Department of Health, Education, and Welfare, certified under the seal of the Department, shall be admissible to the same extent that the original records would be admissible.

§ 290.39 *Depositions.* The deposition of any witness, taken after reasonable notice to the opposite party and at a time and place and before a person designated for the purpose by the Secretary, shall be admitted if the evidence is otherwise admissible.

§ 290.40 *Affidavits.* Affidavits, if relevant and material, may, in the discretion of the examiner, be admitted, but the Secretary will consider the lack of opportunity for cross-examination in determining the weight that shall be given to such evidence.

§ 290.41 *Hearsay evidence.* Hearsay evidence may, in the discretion of the examiner, be admitted even though it does not come within any well-recognized exception to the hearsay rule, but the Secretary will determine what weight shall be given to such evidence.

§ 290.42 *Form of introduction of evidence.* The form of the introduction of evidence shall not be a ground of objecting to such evidence.

§ 290.43 *Copies of exhibits.* When practicable to do so, a copy of each exhibit shall be furnished to the opposing party either before or at the time of its introduction.

§ 290.44 *Judicial notice.* Judicial notice, on request, will be taken of such matters as are noticed by the courts of the United States.

§ 290.45 *Objection to evidence.* If the respondent objects to the admission of any evidence offered against him or the rejection of any evidence offered by him, or to the limitation of the scope of any evidence introduced by him, he shall state the grounds of such objection. If the objection is overruled, he may take an exception.

§ 290.46 *Attorney representing the Department of Health, Education, and Welfare.* At the hearing, the Secretary shall be represented by an attorney designated by the General Counsel of the Department of Health, Education, and Welfare.

§ 290.47 *Filing of briefs.* At the conclusion of the hearing, the examiner shall announce the period of time within which briefs may be filed following the receipt by the respondent of the tentative findings of fact and the tentative order, as set out in § 290.48.

§ 290.48 *Tentative findings of fact.* The examiner, within a reasonable time after the conclusion of the hearing, shall prepare tentative findings of fact and a tentative order, which shall be served upon the respondent or sent to him by registered mail.

§ 290.49 *Exceptions by the respondent.* Within 20 days after the receipt of the tentative findings of fact and the tentative order, the respondent, if he wishes to take exceptions to any matters set out therein, shall transmit such exceptions to the General Counsel of the Department of Health, Education, and Welfare. At the same time, the respondent shall transmit a brief statement concerning each of the exceptions to the actions of the examiner at the hearing, as set out in §§ 290.35–290.45, upon which he wishes to rely. If exception is taken to any proposed finding of fact, reference must be made to the pages or parts of the record relied upon and a corrected finding of fact must be submitted. The respondent, if he files exceptions, shall state in writing whether he desires to make an oral argument on the exceptions before the Secretary.

§ 290.50 *Oral argument before the Secretary.* In the event that an oral argument before the Secretary is requested, a date for such argument shall be fixed by the Secretary or by the Under Secretary, if designated to act in his stead.

§ 290.51 *Issuance of final order.* If oral argument is heard in any proceeding by the Secretary or Under Secretary, the final order in the proceeding shall be issued by the person who heard the argument.

§ 290.52 *Hearing before prosecution.* Before violation of the act is referred to the Department of Justice for prosecution under section 5 of the Federal Import Milk Act, an opportunity to be heard will be given to the party against whom prosecution is under consideration. The hearing will be private and confined to questions of fact. The party notified may present evidence, either oral or written, in person or by attorney, to show cause why he should not be prosecuted. After a hearing is held, if it appears that the law has been violated, the facts will be reported to the Department of Justice.

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